Transcript of Meeting of

Pesticide Program Dialogue Committee

May 25, 2004

For The Record, Inc.
Waldorf, Maryland
(301)870-8025

ATTENDANCE LIST

Director, OPPTS	Jim Jones
Chairperson, OPP	Margie Fehrenbach
User/Grower Groups	Dr. Lori Berger
	Daniel Botts
	Robert Rosenberg
	Bill Tracy
	Rebeckah Freeman
Food Processors	Dr. Steve Balling
Environmental/Public Interest	Carolyn Brickey
	Carol Stroebel
	Dr. Richard Liroff
	Erik Olson
	Patti Bright
	Caroline A. Kennedy
Farmworker	Amy Liebman
	Erik Nicholson
Animal Welfare	Troy Seidle
Chemical Industry/Trade Assoc	Dr. N. Beth Carroll
	Frank Gaspirini
	Stephen Kellner
	Mary Ellen Setting

ATTENDANCE LIST (cont'd.)

	Lori (Hardner) McKinnon
Academia/Education/Public Fo.	Dr. Jose Amador
	Amy Brown
	Larry Elworth
	Dr. Robert Holm
	Dr. Lannell Ogden
Consultant/Private Sector	Patrick Quinn
	Jan Donow
	Dr. Hasmukh Shah
	Julie Spagnoli
	Dr. Warren Stickle
	Jay Vroom
Biopesticide Industry	Gary Libman
Public Health/Nutrition	Alan H. Lockwood, MD
	Dr. Nancy Lewis
State/Tribal Government	Dennis Howard
	John Vickery
Federal Agencies	Dr. Terry Troxell
	Allen Jennings
	Dr. Melody Kawamoto

Nancy Golden

Attendance List (cont'd.)

EPA Lead Region	Diane Sanelli
Also present:	Bill Diamond
	Jay Ellenberger
	Lois Rossi
	Debbie Edwards
	Mary Francis Lowe
	Lynn Moos
	Paula Bodey (Scotts)

P R O C E E D I N G S

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Day One

May 5, 2004

MR. JONES: Okay. We are going to get started here. Time is money. I got a clock ticking. My first order of business today is to introduce my boss, who has graciously joined us here to give us some opening remarks. Susan Hazen who is the principal deputy assistant administrator of the Office of Prevention Pesticides and Toxic Substances is going to lead us off this morning with some opening remarks. Susie.

MS. HAZEN: Thank you, Jim. Well, first of all, good morning. I am really pleased to be here. I've not been able to make it to a number of the PPDC meetings in the past. Schedules just haven't permitted, but I will tell you that years ago when this group was first formed, this was one of my favorite groups to come to. It's the group that I see as sort of helping in the

day-to-day - where the rubber meets the road kind of work of the pesticides program, and the advice that has traditionally come from this group has been the very operational how do you work through some of these major issues and translate them into what is really happening out there. So, I'm really delighted to be here. We've got 12 new members on the group -- always room to bring in some new thinking, some new ideas and representation of -- of different kinds of groups, so again, very pleased that we have new folks us with us today that will help us work through our issues. Yesterday I was at the Administrator's senior staff meeting, and there's a new tracking system that the administrator uses called scout. It doesn't stand for anything. It's not an acronym. Its name really is scout. One of the things that we try and do is make sure that all

upcoming meetings that might be of interest are on that system. So, up pops on the screen OPPTS, OPP, PPDC meeting, and Administrator looked at me, and he said, "I think that's yours. Yeah. Uh-huh. You know, what is that?"

And so I had an opportunity to describe what this group has done and the kind of work that this group is engaged in. He then went round in asking the other AAs, "Do you all have groups like this? Do you have groups that help advise you on this?" And it was interesting, some of the AA-ships -- the water office has a group like this, but there were some that didn't, and his comment back was, "This sounds like exactly the kind of group that I envision when I think about the way I want EPA to operate and the way I want EPA to hear from its stakeholders," and so two things, he now knows what PPDC is, and he sees this kind of group and the things I explained that this group has been doing as very, very important in helping inform the issues which eventually come up to his level for decision-making.

So, it won't surprise me, as the pesticide

program moves along, if he doesn't ask what the reactions from this group will be. So, what started out as an exercise in acronyms turned out, I think, to be an important way to help him understand that this group is really informing what we do.

Well, over the past year we've been dealing with a number of highly visible and controversial issues, some of which I know that you will be dealing with here today and over the course of the months. We have the whole Endangered Species Act work that is ongoing. We see that as extremely high priority and welcome your engagement in that.

We're also going to be focusing on ethical issues surrounding the consideration of data generated by human studies. I'm sure many of you or all of you have been following that issue. It's one that the agency is going to have to come to terms with and to closure on very shortly because much of our work or some of our work is dependent on having policies in place that will help us deal with that. So, we'll be looking to you for that.

We also will be looking to this group -- and I

know that we will be hearing a series of recommendations today on the registration review program. This is something that I personally think is very important as we move along completing tolerance reassessment, and we are on schedule and on track to complete tolerance reassessment for food uses on time.

Jim came to me, I guess, a couple of months ago with this incredibly elaborate schedule that it takes, you know, months to actually figure out, but at the end of it you realize that we do get to where we need to be on time, but when that's done we then have in front of us, I think, the task and the responsibility to assure that we have a process in place to continually review the registrations that we have in place so that we no longer have situations where we have registrations that have been in place for 20 and 25 years without them having been looked at and without them having been reviewed.

We also need to have a process that's going to help us expedite how quickly we can actually review or re-review, if you will, our registrations. We currently do, I guess, about 20 cases and annually, and if you look at what we would have to do with the 1200 active

ingredients that we have, we're going to have to speed that up to close to 80 annually. So, we're going to need a process that is effective that works well for us, that works well for you, and that works well for the public. I think it is going to be a major challenge for us to figure out how to do that, but I think with the help of this group and others that we can. So, that's just one of the issues that this group, I hope, will really help inform us on. There will be others, and I know Jim is going to go into more detail later on.

So, I would just like to welcome you here today. I'm going to stay for a little bit. I can't stay for much but stay for a little bit of the discussion, and I really appreciate you coming, spending your time, helping inform us and look forward to hearing back your recommendations. So, thank you very much. Jim.

MR. JONES: Thanks, Susan. Adam Sharp, who I think many of you know from not just the PPDC but from the other work that he does in the agency not only as the associate assistant administrator for OPPTS but also in recent months since Jean Marie Peltier's departure as the acting Ag Counselor to the Administrator. Adam.

MR. SHARP: Thanks, Jim. I'm going to try this mike and see if it's any better. I think it is, isn't it?

MR. JONES: Yes, it is.

MR. SHARP: I think we have one bad one here. Sorry, Susie.

(Laughter).

MS. HAYSON: Give me the bad mike -- yeah, the (inaudible) is better.

MR. SHARP: Thanks, Jim. Yeah. As -- as -- as Jim said, you know, this group obviously is a group that is very important to the agency. The advice that you've given for years has been invaluable, I know to this -- to the operation of the program, and of course, now I have double interest in it because of the -- my role as -- in the pesticide program but also as the acting ad counsel for the time-being, as well.

So, I know that a lot of the issues that discussed here obviously are very important to agriculture, so -- and to -- and to all of us, and it's good to hear that discussion from that angle, as well. Let me welcome, also, USDA folks. I think also that we

have representatives either here or coming from the services, from Fish and Wildlife Service and from the National Marine Fishery Service, so we have a number of other agencies, as well -- FDA, as well, and hopefully, I haven't forgotten anybody else, but we have a lot of different agencies here from around the Government which is terrific.

As you know, the pesticide program, as we're doing our work, we often run into issues that kind of cross not just our program but other Government agency programs, other interest from other programs. Folks have a strong interest in what we do. We have a strong interest in trying to coordinate our program with other facilities, other functions of the Government, and -- and I think some of those are highlighted very well now with the endangered species discussion we're going to have. So, it's nice to have the participation here from the other agencies. It's invaluable. I think it's something that we've seen probably grow over the years and probably will continue to grow as we're working with other agencies on very specific issues that cut across our program and others.

A lot of good issues on the agency for today, as Susie mentioned. I won't repeat, but I'll echo ESA, the globally harmonized system, endangered species, fees and others, as well as a number of good updates that I know are good for everybody to hear, to talk -- to hear about all the various activities the agency has going on. The program has specifically -- has going on is -- is always something that I know I look forward to just to hear the reaction from folks because people a lot of times, we're wound up in -- in one or two issues and we don't hear about what the program is working on expansively.

There's a number of things we have going on, and sometimes, you know, as -- as a part of an organization that you all are, you sometimes aren't focused on a lot of the other things that are going on, and sometimes you need to be. You need to be aware of some of the other things that the program is doing. So, I think it's a good opportunity for you all to hear about the vast amount of activities that the program does have going on and have an opportunity to ask some questions about those. So, I think that's a positive, as well, out of this meeting.

Let me stop with that and say thank you again for taking the time to be here for the next couple days.

MR. JONES: Thanks, Adam. All right. Well, I'll add my welcome and thank you to Susie and Adam's to returning members, to new members, for those of you who are sitting in for a colleague who couldn't be here, and to the public, whose been able to -- to come today. I did want to -- we'll go around in a minute and have everyone introduce themselves and -- and note their affiliation, but I did want to take one minute to personally introduce the new members who are able to join us here today: Patti Bright from the American Bird Conservancy apparently got through the traffic on 66. Patti, if you'd raise your hand. Amy Brown from the Pesticide Safety Education Program at the University of Maryland, Amy, welcome. Rebeckah Freeman from the American Farm Bureau Federation is joining us here for the first time. Dennis Howard, a colleague from the Florida Department of Ag and Consumer Services, Dennis. Caroline Kennedy, I'm not sure if I saw Caroline -- Caroline from the Defenders of Wildlife is joining us for the first time. Amy Liebman from the Migrant Clinicians

Farm Network, thank you. Nancy Golden, Adam referred to our colleague from the U.S. Fish and Wildlife Services sitting in actually for Greg Masson, who is the official rep from the U.S. Fish and Wildlife Service. Welcome, Nancy. Lanell Ogden from Tuskegee, Lanell, thank you. Mary Ellen Setting, another state colleague from State of Maryland Department of Agriculture is joining us, and Carol Stroebel from the Children's Environmental Health Network, I saw Carol. Thank you.

Welcome all of you who are new to the Pesticide Program Dialogue Committee. We very much appreciate the new perspectives that you are going to be bringing us over the coming days but as we work on a variety of things over the coming months and years. So, welcome aboard.

There are two individuals who are new to the PPDC who were not able to join us today because they had conflicts, Don Carr and John Schell, and I'll make sure I'll make a special effort to introduce them all at our next meeting when they -- when they join us. I need to spend a minute talking about FACA, which is the Federal Advisory Committee Act. That's the law under which the

Government operates when it's getting advice. There are statutory requirements that basically are designed to ensure the transparency in the manner in which the agency -- or the -- any federal agency gets advice, and we are governed by FACA. It insures that we have public notice of these meetings, that we post our agendas on the website, and that the meetings are open and ultimately just designed to ensure that the Government gets advice not behind closed doors, which is certainly something that we in the EPA in the Pesticide Program have tried to be true to in the way in which we -- we do our business.

The importance of our work before -- when we're not in this meeting is important to stress, and when I say "our" I mean collectively "our". These meetings can be very effective if we, in the Government, invest in making sure that we have teed up issues in a manner that allow you to participate and to give us advice. Likewise, it is very important for you to engage not just on the plane ride here, on the Metro trip in but in the various mechanisms that we create to participate to help us understand the advice that you are -- you are trying

to give. The issues that we deal with in the Pesticides Program, and I think that it's not -- it's certainly not unique to us in the OPP, in the EPA, or in the executive branch, they are rather complex. It is very hard for us to completely explain them in 45 minutes. It's very hard for you to completely understand them in that 45 minutes, and it's very hard to get back advice in the remaining 45 minutes that we'll have for our topics, and so one of the things that we've tried to do over the last year or so is to put together workgroups that work issues in between meetings.

We've tried to provide material beforehand to allow you to familiarize yourself with the issues, and I just want to reinforce the import of us doing our job making sure that the issues get teed up in a way that they're understandable to you and that allow you to provide us meaningful advice, but it's equally as important for you to participate in the various mechanisms that we create, and when we all do that, I find that we have rather effective meetings that give the agency what it's looking for, which is advice on some very difficulty issues. When we fail on our part, it

doesn't work. If you fail on your part, it doesn't work. We both need to be engaging in that manner. We've heard you over the years that you really want to engage on issues that are important to us. We always give you an opportunity of identifying issues that you think are important. I think our agenda actually reflects. I think environmental marketing claims is one of those areas, but when they are important to you, they are often important to us, as well, but I think we have found a nice balance of issues that we are very interested in getting advice on and issues that you've expressed some interest in giving advice on.

The agency basically -- and I'll go over it in a little more detail in a second. We -- we typic -- we try to avoid just a talking head kind of meeting where we are up here just blabbering on, and on, and on about what's going on and what we're doing and give you five minutes to give us feedback, but we have sort of three different kinds of issues that we bring forward.

We do give you some updates, and those are sort of the talking head kinds of things where we're saying here's what's going on, it's a very interesting topical

issue that we think it's important for you to have knowledge of. The next thing we do is we -- what I call sort of accountability sessions, where we say, here's an issue that we have discussed previously, and here's what EPA has done to follow up on that issue. We also have what I call accountability sessions around here's generally what we're doing in the Pesticide Program, whether it's giving you a status report on tolerance reassessment, re-registration, or registration. The third area is where we're sort of taking a pretty meaty topic and discussing it and -- and -- and getting advice from this committee, things like registration review, things like endangered species, those are things in our topic today that actually fall into that latter category.

We try to -- we try to sort of get the agenda in a way that we've got balance between those three different kinds of discussions, some of them very much just our reporting out, others of them where we're having a group of you reporting into us what you've done over the last six months.

All right. Let me just spend a few minutes on the agenda. I think it's pretty self-explanatory. This

morning we're going to start with a report from the PPDC workgroup on registration review. We're going to move onto an issue that we've brought to you before. It became clear to us that we needed to give you more information, that's the Global Harmonized System of Classification and Labeling. It's something that's going to happen, and we're very interested on getting some advice from all of you. We have -- then before we break for lunch, we're going to do some program updates and some pretty topical issues from human testing to the notice on mosquito labeling and human -- and the Pesticide Safety Education Program funding. We'll have an hour for lunch. We'll come back to what may be the most topical issue for those of us working in the Office of Pesticide Programs, and that's our endangered species program, and we've got a -- almost two hours for that discussion, and we'll close the day, at least in the -- in the -- sort of the topical way, with a discussion on environmental marketing claims, which is something that I am, as the director of the Office of Pesticide Programs, very interested in getting some advice on. It's an issue that in my 10 years in the Office of Pesticide Programs

comes up constantly, and I think we are ready to get some advice from a broad group of stakeholders as to which path we should follow. We end every meeting with public comment, as it is required under the FACA rules, and that anybody in the audience is able to provide comment. If you do want to make a comment, I do ask that you let Margie Fehrenbach -- Margie, raise your hand -- know so we can figure out how to manage that -- that last session.

We'll start tomorrow again at 9:00 with a discussion of PRIA, the Pesticide Registration Improvement Act, which, if you are not aware of, you certainly should be, focusing on process improvements and a worker safety set-aside. It's part of PRIA. We'll have some more programmatic updates, actually two sessions where we're given programmatic updates, and broken in between amongst that will be a discussion amongst us for future topics.

We have some ideas about areas where we are interested in getting advice, and I'm interested to hear some of your ideas, as well. So, that's the -- the agenda for today and tomorrow.

Before me move on to our first topic, I would ask that we go around the room, and if everyone could introduce themselves and your affiliation, and if you're sitting in for someone, mention that, as well.

We'll start with Berlison (phonetic).

MR. SMITH: Burleson Smith, USDA.

MR. JENNINGS: Al Jennings, USDA.

MR. TROXELL: Terry Troxell, FDA.

MS. KAWAMOTO: Melody Kawamoto, CDC NIOSH.

MR. LOCKWOOD: Alan Lockwood, Physicians for Social Responsibility.

MS. Crenenzy: (Steptoe and Johnson) sitting in for Has Shah, ACC -- or ACC Biocides Panel.

MR. ROSENBERG: Bob Rosenberg, National Pest Management Association.

MS. SANELLI: Diane Sanelli, the EPA's Regional Office in Denver. I'm sitting in for Sadie Hoskie.

MR. VROOM: Jay Vroom (Crop Life America).

MS. HALL: Susan Hall from PETA. I'm sitting in for Troy Seidle.

MR. HOWARD: Dennis Howard, Florida State, Florida Department of Agriculture.

MS. SETTING: Mary Ellen Setting, Maryland Department of Agriculture.

MS. OGDEN: Lanell Ogden, Tuskegee University.

MR. QUINN: I'm Pat Quinn with the Accord Group, a Government affairs firm here in Washington.

MS. LEWIS: Nancy Lewis from Husker country, the University of Nebraska, nutrition and health sciences.

MS. GOLDEN: Nancy Golden, Fish and Wildlife Service sitting in for Greg Masson.

MS. HOLM: Bob Holm, IR-4 Program, Rutger's University.

MS. CARROLL: Beth Carroll, Syngenta Crop Protection.

MR. LIBMAN: I'm Gary Libman, Bio -- Emerald Bio-Agricultural.

MS. BRIGHT: Patti Bright, the American Bird Conservancy.

MR. ELWORTH: Larry Elworth, Center for Ag Partnerships.

MS. DONOW: Jan Donow (phonetic) Proctor & Gamble sitting in for Len Sauers.

MS. BROWN: Amy Brown, American Association of

Pesticide Safety Educators.

MR. GASPERINI: Frank Gasperini, Responsible Industry for a Sound Environment sitting in For Allen James.

MS. BRICKEY: Carolyn Brickey, Protected Harvest.

MR. BALLING: Steve Balling, Del Monte Foods.

MS. KLINE: Bridget Kline with the Consumer Specialty Products Association. I'm sitting in for Steve Kellner.

MS. KENNEDY: Caroline Kennedy, Defenders of Wildlife.

MR. BOTTS: Dan Botts, Florida Fruit and Vegetable Association.

MS. LIEBMAN: Amy Liebman, Migrant Clinicians Network.

MR. AMADOR: Jose Amador, Texas A&M University, the Agriculture Research Extension in Weslaco, Texas.

MS. BERGER: Lori Berger, California Minor Crops Council.

MR. NICHOLSON: Erik Nicholson with the United Farm Workers of America.

MS. SPAGNOLI: Julie Spagnoli, Bayer Animal Health Division.

MR. VAN DON: Garrett Vandon (phonetic), National Cotton Council sitting in for Bill Tracy.

MS. STROEBEL: Carol Stroebel with the Children's Environmental Health Network.

MR. STICKLE: Warren Strickle with the Chemical Producers and Distributors Association.

MS. FREEMAN: Rebeckah Freeman with the American Farm Bureau.

MS. MANELL: Martie Manell, Deputy Director, Office of Pesticide Programs.

MS. LINSEY: Ann Linsey (phonetic), Pesticide Programs.

MR. JONES: All right. I did want to mention we've had a few changes since we've last met in our management team. Most of you, if not all of you, know Lois Rossi and Debbie Edwards, who are here, who have switched jobs in the last year. Maybe they're not here right now. Lois is now the director of the re-registration division, and Debbie is the director of the special review and re-registration. They'll be on the

agenda later today, and Bill Diamond -- Bill's in the back -- is the new director of the Field and External Affairs Division. You'll be seeing a lot of Bill over the next two days. That's the job that Ann Linsey had, who is now the deputy director for program.

Okay. Well, let's get started. Registration Review, the workgroup, the PPDC workgroup that has been working very diligently on this effort, I just want to briefly say that I feel as if we set a new standard for policy advice, regulatory advice in this exercise, where early on in our work on registration review, we created a PPDC workgroup that's been working quite hard to give us advice before we have a proposed rule, and what we're going to hear this morning is sort of a status of where we are in OPP and the recommendations that we are getting from the workgroup. Actually, the recommendations, technically, are recommendations to the PPDC. The PPDC then will give us advice as to whether or not we should be following those recommendations. All right. Susan Lewis and Jay Ellenberger will be leading us in this discussion.

MS. LEWIS: Good morning. I'm Susan Lewis.

Today you're going to hear sort of a three part presentation on registration review. Because we have some new members at PPDC, I'm going to briefly give a background of what has happened to date, in essence, since FQPA was enacted. Then, you're going to hear from three of the PPDC workgroup members on issues that they've actively been working on since January, and then then, thirdly, Jay Ellenberger will wrap it up and talk about next steps, and then we'll open the floor for a discussion. Next slide.

So, in 1996, the Food Quality Protection Act had in it a mandate for registration review. There's a portion on PIFRA (phonetic) called PIFRA 3-G that now calls for a period review of all chemicals.

Before, when we were doing re-registration, those chemicals subject for evaluation were those chemicals registered pre-1984. Since 1984, we've registered over 400 active ingredients. These compounds will also be subject to registration review.

I think you heard earlier from Susie that our universe is roughly 12,000 -- excuse me -- 1,200 chemicals. So, that's a huge workload that we're going

to have, 1,200. When you're talking about products, it's probably over 20,000 products.

The finding that we must make is no unreasonable risk. It's a very similar finding we make today under re-registration or a new active ingredient, and again, the goal is every 15 years. So, there will be a continual cycle of a reevaluation every 15 years. Next, please.

So, one of the first things that the agency did was issue an advanced notice of proposed rule-making back in April of 2000, and in that we laid out we laid out our initial thinking and asked for comments in several areas.

After we got back the comments, and there were roughly eight commentors, the group, you know, looked at where we needed to go and actually came to the next PPDC meeting, which was in April of 2003. It was at that meeting, the PPDC meeting, that they were charged with forming a work group of members from PPDC to tackle some of these issues and give advice and recommendations on moving forward with registration review. We have 23 members that are diverse memberships from industry, to grower groups, to environmentalists that comprise this

workgroup. Next.

The first -- thanks -- the first three issues that were tackled by this workgroup were how are we going to develop a schedule for registration review? You've heard the number of compounds we're going to have to do, and every 15 years, that means 80 chemicals a year.

So, number one issue, they said, was scheduling of registration review. What kind of review would be necessary was the second issue, what level of review, and the third dealt with public participation. Next, please.

So, the recommendations that were presented out to the PPDC was that for this large task we really needed a predictable way to schedule, and they knew what they didn't want the scheduling to be. They didn't want it to be labor-intensive, a resource, or subjective. They wanted it to be based on every 15 years, and in essence, based on the date of either the first registration or the last significant regulatory action, such as re-registration decisions.

We also realize that this universe of chemicals is constantly changing. We continue to register new active ingredients, and we also occasionally have some

compounds that are withdrawn from the market or are cancelled.

There will be reasons at times where we will need to deviate from the criteria for scheduling, and that was recognized, but it was suggested that we develop a criteria for how and why we would deviate from this scheduling, and if we did that, we would also publish a comprehensive schedule in the federal registry with regular updates so people would have very fair notice of the compounds we're going to be reviewing. Next.

So, the next issue was what are the reviews going to look like? And the sentiment was one size doesn't fit all. Some compounds have very difficult risk issues, complex use. Other compounds may have very limited exposure and very low risk. So, we wanted to have a streamline process that would have been relatively simple for those compounds that were current, the risk assessments were up-to-date, there were no issues, and there were no data gaps, but the workgroup has often referred to this as an easy off ramp. In essence, you look at the baseline of what you have, you come to the conclusion that everything is okay, and it is then deemed

all right. However, there are also going to be compounds that have more complex issues, and they're going to require a much more robust assessment. Because of the number of compounds we're going to be doing a year, roughly 80, we are going to need to be efficient on our resources. Next.

So, the third issue which dealt with public participation, it was concluded that the best way to ensure public participation was to, again, publish a schedule far enough ahead of time so that all stakeholders had knowledge of which compounds would be going through the process. With this knowledge, they then could participate very early on, even prior to the agency developing new assessments.

Just as we do in reevaluation today, participation on stakeholders could involve things such as use profile, risk assessment, risk benefit analysis, and mitigation. So, you can see that there's public involvement throughout all phases of this. Again, the public participation would be flexible because some compounds may not involve too many risks, and we felt that those -- public participation would be available,

but on those compounds that are more complex there would probably be more extensive participation. Next.

Another part that could really help ensure public participation would be, as we're using now e-dockets, and this would be a way to ensure sort of a continual information flow of the information we have at hand. Next.

So, that concludes the three key issues that had been worked on previously and presented earlier to PPDC meetings. Now, since January of 2004, the workgroup has been working on three additional key issues which you'll hear about shortly. The first one is which action initiates a pesticide registration review. The second one is early submission of test data and other information, and third, what does a registration review decision look like?

Ray -- Ray is going to present the first issue.

MR. McCALLISTER: I'm Ray McCallister (phonetic) with Crop Life America, and it's been my privilege to work on this -- to be a part of this work group over the several months. There are three principal considerations we took into account in making recommendations regarding

how you initiate registration review. First, is the schedules. We looked at both a long-term schedule and -- and a shorter-term or annual schedule. Since it's a program that addresses all active ingredients, it's a 15 year schedule. We felt it was important to have it laid out ahead of time what both registrants and other stakeholders could expect.

We also took into account the background information that is available on each active ingredient and how the stakeholders and registrants would be informed of what that body of information is and then looked at the basis for review: What's the starting point for the review of each chemical? Next line, please.

Our recommendations for a master schedule would be to publish in the Federal Register at the initiation of the registration review program a master schedule to list all of the active ingredients subject to registration review, which is the body of active ingredients registered with the agency, and with that, a target year for review, not -- this would not be a precise schedule but a target -- a chronological order of

the reviews to take place. The year for that -- that target year for review would be determined by the date of the initial active ingredient in registration or the re-registration eligibility document, the completion date for that document.

There would be a public comment period on this schedule or anyone in the public to suggest changes or recommend changes to that master schedule, but I would not see a reason for comments necessarily to delay initiation on this special review -- or excuse me -- registration review program, and this schedule would be subject to periodic updates, probably on an annual basis. Next slide.

On an annual schedule, the agency could revise the master schedule with any adjustments which could take into account productivity and how long it takes to complete the registration and -- or the registration review and the experience they gain along the way.

An annual schedule would list the specific A.I.s coming for that year and assign them a date for initiation on their respective actions. This could also be published in the Federal Register Notice and on OPP's

website. There may be ways to combine this annual schedule with notification of the public of initiation of those individual registration reviews for an active ingredient to cut down on having to publish 80 separate Federal Register notices in a given year, and -- and again here, the revision to the master schedule published on an annual basis would be subject to a public comment period. The next slide.

At the initiation of that special review, the agency would place the following types of information in an electronic docket where they're available to anyone via the internet that would list the registrant's holding product registrations for that active ingredient or case, if it includes multiple active ingredients, and the reason for grouping active ingredients as a case would -- would generally be that they're closely chemically related and share at least significant elements of a common database for their review. It would also include a listing of the registered product containing that active ingredient, a separate listing of the use sites where that product -- that active ingredient is registered for use, a list of any tolerances for residues

in crops and raw agricultural commodities, a bibliography of the data that EPA has which have been used for previous registration decisions or have been submitted since previous registration decisions and a listing of any outstanding data call-ins which are applicable to that active ingredient. Next slide.

It would also outline the most recent risk assessment in each of several major categories, whether its dietary risk assessment, endangered species, worker exposure, et cetera. It would include a listing or outline of known agency concerns about that compounds, whether they're health related or environment related. It would include information about any review activities that are in progress for that chemical. These would be major reviews such as a dietary risk assessment or if there is some special review going on. This isn't reviews of individual uses or reviews of individual products that have been applied for. We would recommend a brief summary of adverse effects data, not necessarily a detailed accounting of all adverse effects data that have been reported. That is something to be -- take

place during the review, itself, and there should be an outline of the significant label issues, if appropriate, such as the restricted use classification or requirements that apply to all labels containing that particular active ingredient. The basis for registration review should be the data and information that the EPA has in hand at the initiation of the review. We don't believe it should be a process where, at that point, the EPA is calling in a lot of data which is going to take years to submit and then years to review before you arrive at a decision. That may be a result of the review process, the registration process, that additional data required but not a necessity to start the process, and the registration review should be governed by the requirements, data requirements and registration policies in effect at the date of that initiation.

Do we want to take any questions now or wait until we are done?

UNIDENTIFIED MALE: Let's move on.

MR. McCALLISTER: Okay. We'll move on then.

MS. HAYSON: Patti Bright.

MS. BRIGHT: As Susan mentioned earlier, one of

the things that the working group was asked to look at was submissions to support registration review. In terms of considerations, the working group felt that it was very important that the process be an open and transparent process and that it encourages all stakeholders who possess valid or pertinent information to be able to submit that information.

We also felt one of the considerations was that the information needed to be submitted as early as possible, one, so that EPA could identify any data gaps so if information needs to be brought in, they can do that, but also so that if there are a number -- if there are different concerns or issues that stakeholders want to raise, those can be raised early in the process and addressed. We feel that this will really help to streamline the process and will help avoid EPA having to go back and reevaluate or rework things if issues were to come up later in the process. Next line, please.

So, who exactly would be submitting registration information? Obviously, the pesticide registrants would be submitting information. We, also, as I mentioned earlier, we want this to be an open and inclusive

process. So, we would want other stakeholders, including growers, commodity groups, public interest organizations, as well as members of the general public that have information that they would like to submit. We would also like to see Government agencies involved. This would include agencies, of course, like USDA, IR-4, CDC, the Fish and Wildlife Service, as well as universities and agricultural extension agencies. Next line, please.

Some of the recommendations that the workgroup had, as mentioned earlier, is publishing a schedule for review so that all the stakeholders would be aware of what's coming up. We would like EPA to very clearly articulate the guidelines and the data needs, again, that all stakeholders are on the same page. We would like them to describe data submission requirements and explain how that data will be used, and then in the event that there is additional information that -- that EPA needs, they would still be able to issue data call-ins when necessary. Next page.

In terms of our recommendations, we also think that it is important to provide a framework for communicating those information needs to all the

stakeholders. One of the things that the working group thought might be useful would be to create and use a list serve so that interested stakeholders could get information on active ingredients in the registration review.

I think that was it for me, wasn't it?

MS. HAYSON: And Sue Crusinsky (phonetic) is going to present the third issue.

MS. CRUSINKY: So, at the end of this process there will have to be a decision made or several decisions made perhaps, and so we looked at procedures for making that decision, the possible conclusions that would constitute the basis for the decision, and then the communication of the decisions.

As far as procedural options are concerned, we thought, well, you know, with re-registration there has been this two step process. You do the -- make the findings -- the risk assessments based on the active ingredient or active ingredients. Once that -- once that set of decisions is made, you then take a look at the individual products, and there has been delay in that with re-registration because there have been data needs,

but we don't anticipate those in this particular process. The other would be simply to make the registration review decision based on individual products without any AI specific step. Next slide.

And we thought that, again, it's important to make the scientific findings first on the basis of the AI or the case because there could be multiple A.I.s in the case, and then this should be followed by a review of the individual products, and the product labels would have to comply with all decisions made for the AI or for particular use of the AI and also conform with all current label policies and for products with multiple A.I.s, they would have to go through this label reevaluation as each AI comes up. I don't think there's any really other practical way to handle that.

Again, we don't anticipate that there should be much in the way of delay from making the underlying AI or case decision to getting to the labels because there really shouldn't for the most part -- I think it would be very unusual if there were needs -- judged to be a need for product-specific toxicity data. Next line.

Okay. The meat of the whole thing, possible

review conclusions, and Susan discussed earlier the easy off ramp, and that is that basically there are no changes needed beyond possibly some generic label changes for the individual products, and that's just to make sure that they're up to current standards, but basically all the risk assessments look good, no -- no reason to reassess any of the conclusions be it dietary, occupational, ecological.

Another conclusion could be that there's some mitigation required, and this would, in all likelihood, have to be communicated through the labels. So, the individual product labels would be required to be amended to reflect whatever that particular mitigation change may be, as well as updating -- making any generic label changes. Next slide.

It's also possible that there will be a decision that data are needed to update or supplement the database, and so basically this could -- this could be, in part, a conclusion that could occur with the easy off ramp or mitigation, and that's where, you know, we have sufficient support for continued registration, but we really think that this database should be completed to

satisfy our needs. I work in the antimicrobial area, and one of the areas that I would think of would be exposure data, for example, because this is really an area where there's not a lot of data, and so you would be refining the information available to the agency.

You could make a final decision. You could make an interim decision, I guess. I mean, these are, you know -- again, we're looking at flexibility for the agency to fit the situation, and again, you'd make product label changes based on the elements of the decision. Next slide.

And then there could be a conclusion -- and I don't think that we would anticipate this to happen a lot, but it would be for whatever reason, the agency determines that it cannot make a risk decision. Maybe it's an occupational or maybe it's an ecological, and so a data call-in is going to be issue, and the review, the final --

(Tape 1, Side B.)

MS. CRUSINKY: -- and will have to be deferred until the data are submitted. Another conclusion is that the active could be voluntarily cancelled, and the final

conclusion would be that the agency would initiate the cancellation or suspension procedures under section six of (inaudible). Next slide.

And this summarizes everything we've talked about. There is your answer to anything you want to know. Now, there -- you don't have to look at it on the screen. There is a copy in your hand-out (laughing). All kidding aside, though, this really is as good as it gets in terms of trying to serve up all of the different options that might be available, and thanks for this has to go to Julie Spagnoli, who really did all of the major drafting on it, plus thank God somebody knows how to draw these boxes and arrows because it's beyond me.

Seriously, though, this is -- this does summarize -- and I don't think that we need to go through it right now, although certainly as people have questions, I mean, we could refer back to this perhaps, but I think you've probably all had enough of this for the moment. Next slide.

So, you have to communicate this decision at the end of the day, and again, we're looking here to permit the agency the kind of flexibility and registrants the --

the flexibility that's needed to meet whatever the particular issues are raised in -- for a particular AI, a letter to the registrants saying everything's fine or letters to registrants -- and again, I'm not sure that all the -- all the issues here have been worked out in terms of how you'd require the label amendments, but that's something that I'm sure is being looked at right now -- obviously DCIs, when they're necessary, also, public communication, again, in keeping with making this a completing transparent process.

There might be agreements between registrants and EPA that set certain conditions, and obviously the final conclusion here is that failure of individual product registrants to amend their labels could lead to cancellation.

MR. ELLENBERGER: Thank you, Sue. Does this work at all?

MS. HAYSON: Yes.

MR. ELLENBERGER: Okay. I'm Jay Ellenberger with the Office of Pesticide Programs, and as Susan said in the introduction, I'm going to finish this presentation up and give a summary of -- of what the --

what the agency's plans are for moving forward and developing the proposed and then the final rule now that we -- now that the program has received advice and recommendations from PPDC working group. The first thing I thought I would do is share with the -- a summary of our schedule. How do we achieve the goal that Jim Jones mentions in his opening remarks, as well as Susan Hayson about having the program ready, and actually in place, and implemented by the time that we complete tolerance reassessment in winding down our current re-registration program in August 2006. So, that's our goal, and so how do we get there? Well, sort of working backwards, we figure that we got to have our final rule of the registration review program out no later than mid-2006. This is really -- between now and then is quite an aggressive schedule. It seems like a lot of time -- geez, that's more than two years away, but all of the steps that a regulatory agency like EPA has got to do to get a final rule-out, there's a lot of things that happen internally as well as externally.

So, preceding the final rule a year earlier, we are proposing to get the proposed rule out in February

2005, and before then, we know that we've got to finish drafting the proposal, get it through internal OPP review and internal agency review, but even to get that far to draft the proposal to get it through the system, we have -- we need to develop a sound economic analysis of what the costs are going to be. What are the costs to the agency? What are the costs to industry of implementing this new program? And I will talk about that -- the need for that economic analysis in the next few minutes.

So, what are the next steps? How do we get there? How do we reach that goal? Well, one of the first things that we're doing is, in addition to drafting the proposal, as well as the proposed rule in the preamble, we are also working on developing the schedule that you've heard about.

There are over 1100 active ingredients, and considering how we're going to work through these 1100 active ingredients on a schedule of the taking -- taking first those that have the oldest risk assessments, we've got to figure out what are the 1100? How do they fit together within logical, chemical cases starting with or using the current re-registration chemical cases that we

had in place over the last 15 years and put them in a chrono -- in a chronological order that we've talked about. So, we're busy doing that, and we're pretty close to having that complete and then also develop the credible economical analysis that I've mentioned in order to implement the rule, and we want to test -- test drive this proposal. Based on the recommendations and advice that the workgroup has given OPP and our own thinking, as well, putting it all together, we want to make this really will work. So, we've planned to conduct a pilot process starting very quickly -- very soon, I should say, over the next month or two. We went to identify a sufficient number of pesticides that would represent the different kinds of pesticide types, you know, the conventional pesticides, the anti-microbials, as well as the biochemical, biological pesticides, and once we've identified that universe for the pilot, then have an internal OPP workgroup of scientific and regulatory experts for those chemicals, do a cursory review, looking at the kind of information that Ray McCallister talked about for those chemicals.

So, we'll be pulling together the current risk

assessments for each of those pilot chemicals, the use patterns, looking at the labels, and comparing the -- the last risk assessment for those against what do we currently know about risk assessment for these kinds of chemicals and these kinds of uses as the -- I mean, what's changed? Has the science policy changed, the data requirements changed, legal consideration of statutory considerations, trying to figure of what the differences might be.

As a part of that pilot process, the expert work will be in reporting the findings. How many of the pesticides in the pilot don't need any additional data? That -- everything's fine. There's really been no significant changes in anything, or how many need a new risk assessment? For example, are they likely to need an endangered species risk assessment? And we will hear more about that later this afternoon. Are new studies needed, data gaps? Do DCIs have to be issued, et cetera, et cetera, just trying to figure out what the differences might be, the frequency of those differences, and then that would -- that would provide us the kind of valuable information that we would need to do our economic

analysis for estimating the costs for both the agency and for registrants. It would also give us an idea of the feasibility of this process that we've designed with the advice of the workgroup. What's the appropriate level of review for this? Is it going to -- is it much more detailed than we've led to, you know, think this -- think about it or not and then also give us an idea of what kind of adjustments perhaps we need to make to the process and how we need to reflect that in our -- as we're writing the proposed rule, and then last, what are the -- what are the resource implications for the program and for industry?

As we finish tolerance reassessment and the -- the traditional re-registration program, figuring out how to move those resources -- transfer those resources within the program to do registration review, what is the right kinds of mix both in the technical expertise, as well as just numbers of -- of staff?

So, in conclusion for this, the workgroup's advice, recommendations have been really very beneficial to the program. Susan and I want to thank each and every one of the workgroup members, and by the way, I believe

on the last page on your packet for this is a -- is a list of all the workgroup members and their affiliations.

They're really been instrumental in helping us think through what are the significant issues, and what are some of the ideas, and pros, and cons about how to deal with each of those issues? So, it's been very good in helping us formulate the process, and we -- we really believe that the pilot -- doing the pilot in the next couple months is -- is the right approach. It would really be very beneficial to us, and I think in the long-term could be very beneficial to the regulated community, as well as the general public and other stakeholders in making sure that we've got a process that works, that is smart, that is efficient, that it can -- it will enable us to crank through the 80 or so active ingredients a year that we'll need to do meet that goal of every 15 years, and we are using these recommendations helping us think through as we draft the proposed rule for publication in early next year.

So, with that, I would like to turn it back to Jim.

MR. JONES: First, if we could -- any other

members of the workgroup, PPDC workgroup, want to offer any insights, observations -- Carolyn?

Carol, go ahead.

MS. BRICKEY: Yeah. I -- first, I wanted to thank my colleagues on this workgroup for doing such a good job. I wish I had been involved more than I have, but I guess I have three thoughts about the completed report. First, I think that one of the difficulties the agencies always struggle with is where's the right balance in registration review? You know, do go all out and look at everything endlessly? Do you worry about dried blood? You know, how -- how do you do that, or do you go to the other extreme and not do enough and just say everything's fine?

So, I know there's a tension involved in that, and there naturally would be. So, I think it will be really important in this pilot to figure out, you know, what is the standard you're going to use for the easy off ramp? You know, how are you going to figure that out? That is critical for you in making this -- you know, looking at 80 chemicals a year, an efficient process, and the second thing is it's always struck me that DCIs are

-- are -- or the DCI process, I should say, is a crude tool. I've never liked it. It's a lot of paper. It's a lot of time. It's expensive. You have got ONB and fight with them about whether you get to issue one or not, and I would really look at refinements of the DCI process that could be used that wouldn't require, you know, routine DCIs.

I mean, I know that there is extraordinary circumstances that occur where you do need to issue a DCI if you're going to change part 158, but I would really look for some refinement on that to make it easier, and cheaper, and more targeted.

Thirdly, I would like to think about a way to reward early date of submission, and I know that's one of Jim's specialties is thinking about that kind of process, but I think that would be a good way to help -- help you figure out the easy off ramp, and if you connect those two things together, I think that would be really beneficial.

MR. JONES: Good -- good issues, Carol, and I think -- I think the easy off ramp issue, I want to say we'll know it when we see it, we do the process, but

again, I think it's the kind of thing that we're going to have to work through and I -- with a lot of new process issues, you know, I'm a believer that until you do it, it's hard to anticipate exactly what it's going to be like, and so, you should really test your planning, and you had mentioned, you know, chemicals like dried blood, garlic, you know, oil of citrus, et cetera, et cetera. I can't imagine that those are going to be the difficult ones compared to some of the more conventional chemicals or maybe some of the anti-microbials where there's -- where we're struggling with database -- database adequacy, but again, it's the kind of thing that we've talked about internally for the expert group to how we're going to do that, and we're going to have to just work through it, and I -- perhaps as we work through it that will enable us to explain more about that in our preamble to the proposed rule.

MS. BRICKEY: Well, I would advise you strongly not to say you'll know it when you see it. I think that's deadly. You're going to have to -- I mean, maybe if you do -- I don't know what your pilot's going to be, but if you do 10 or 15 chemicals and look at those,

you'll start to get some ideas about what the criteria should be, but I don't think you're going to know it when you see it.

MS. HAYSON: Go ahead, Julie.

MR. JONES: Julie.

MS. SPAGNOLI: Yeah. Just to comment on the easy off ramp, and I think when we say we know it when we see it, it's really not going to be a single glance, and Sue is so kind as to blame me for those flow charts, but if you really look at this, this really shows that there is no single, easy off ramp, that's it's really a multi-step easy off ramp, and if you go and basically, at each step, if you can say, no, there's not an issue, no -- if you kind of go down that middle row, that's essentially your easy off ramp, but it's not a, gee, we'll just know it when we see it, it's basically a series of questions that you look at, and if you can in each of those cases say, no, we don't have a concern or all the data are there, then that becomes the -- the fast route, or as Sue had said, you know, there may be -- it's a semi-easy off ramp where you get down to the third box, but you say we need some label changes. Oh, do we have a pointer? You

know, where --

(Tape 2, Side A.)

MR. SPAGNOLI: -- saying what can we do to try to be as efficient as possible and not spend a lot of time going through all of this if we can answer questions and do this, and so that's, I think, how we envisioned this. So, I said it's really -- when you first look at a flow chart, it always looks really complicated, but when you really start looking at these are just steps in each -- in the process.

UNIDENTIFIED FEMALE: And Carolyn, on the data call-in front, we're actively looking at that issue as to when is a data call-in needed? When is it not? It's an ongoing effort.

MS. BRICKEY: Well, it's not so much yes or no, it's thinking about lesser tools that you can use --

UNIDENTIFIED FEMALE: Yeah.

MS. BRICKEY: -- which I think is more important.

MR. JONES: There's four other names up. I'm not sure who's next. Gary?

MR. LIBMAN: I echo what Carolyn said. It's a

great job on the team. I wish I could have participated a little bit more, but I always seemed to be traveling when we had these meetings. My question from a registrant perspective is the products with multiple A.I.s, I don't have a sense of what number of products -- what percentage of products -- maybe Jay does or maybe you do, Jim -- is it 10 percent of the products are they multiple -- multiple ingredients because those -- those things, I would hate to see those have to follow, you know, more than once every 15 years. That's -- that's where I think there would be some problems.

Do you have a sense of how many that is, Jay?

MR. ELLENBERGER: I don't. I'm guessing somewhere in the neighborhood of 20 percent, but that's just a guess --

MR. LIBMAN: Twenty percent? Okay. Yeah.

MR. ELLENBERGER: -- on my part. I mean, I -- maybe 30 percent --

MR. LIBMAN: It would be nice to have a mechanism where we could just do those -- each product once every 15 years, you know, and I understand that there is an IA in year three and also in year eight, and

what do you do between the interim years?

MR. JONES: That's certainly something that when we -- one of the benefits of publishing the entire schedule -- one of the questions we can ask in doing that is for helping identifying where there may be active ingredients are far apart in the schedule, but they're shared in the same products that we can move things around to achieve what you're -- what you're attempting to achieve, Gary, is an appropriate objective to have.

UNIDENTIFIED FEMALE: Thank you. I just want to comment on the DCI issue. As you look at whether to issue a DCI or not, be very, very careful in how you handle it because it is one of the few mechanisms that the basic registrants have in being compensated for the data that they develop.

MR. JONES: Thank you. Bob.

MR. ROSENBERG: Yeah. I guess I have, it's two comments: One is despite the fact it's not re-registration, it still seems like a pretty, pretty substantial commitment of resources. Has there been any effort made at all to try to even estimate the amount of resources that would be necessary to do even a single

registration review, and I guess what I'm getting at is are we setting up a re-registration Albatross where we've got a program that's destined to fail, and 10 years from now Congress is going to be holding oversight hearings asking where you're 10 years behind in keeping up with the statutory schedule would be the first thing, and secondly, is not related to that at all. As imposing as the burden is to the agency to go through 80 actives a year, in a similar way, it's also fairly imposing for small, unsophisticated organizations like the one I represent to sort of keep up with 80 chemicals a year, and you might be juggling two or 300 different chemicals, albeit we don't use all or even a small fraction of them. So, I would encourage the agency -- and I think Susan or maybe Patti mentioned it -- to try to be thinking about some innovative ways to allow for some kind of easy stakeholder input, and you know, I -- there's probably a half a dozen things that could be done, but again, I would like to kind of keep that at the forefront of the agency's thinking.

MR. JONES: Thanks. I don't think this is -- we certainly are planning the process, and using a pilot, I

think one of the purpose is the pilot will give us an indication of the resource costs to do each one on an average. So, that will be very useful to -- for us, and also, as I said, give us an idea of what we think the cost implications are for a company. What's likely to happen as far as new data, or label changes, or whatever? So, I think it will be very, very useful to us, and I can't imagine proceeding without having that kind of background information.

You know, we're -- the -- meeting the goal of 80 decisions a year, essentially, it is daunting. It's essentially four times what we're currently doing, and we really tried to think outside the box of doing what we've been doing for the last 15 years or so with re-registration and try to think very differently and try to think how to do things even more efficient than the changes that we've made over the last five, 10 years with our re-registration process to get at the decision -- at a 3C5 decision, and you know, I'm a firm believer that the more you do this, the more experience you get in the new process, we'll learn, make more changes, become more efficient, reinvent, reinvent, and reinvent. So --

Allen?

MR. JENNINGS: I have a question that's related to the overall mission of the agency to protect public health and the environment, and that is for some of these A.I.s there is quite a lot of active research going on, and 15 years is almost an eternity in terms of the progress of science.

What provision, if any, is there for an early re-review of an AI when, if -- if, in the event, that significant new information about neurodevelopmental toxicology or something of that nature comes up? I think there needs to be a fair balance between harassment of the registrants and protecting public health. How is that going to work?

MS. HAYSON: One of the items we truly considered in registration review is we still have ongoing programs. Those don't stop, including our special review options. So, if there is a compound that poses, we believe, significant risk in a particular area, we will deal with it under what we would typically have done under a special review. So, we wouldn't wait for 15 years if something came to our attention.

MR. JONES: But also, just to add to what Susan said, we've got the 6A2 program, so as new studies come in that show new effects that go beyond what our current database shows or new kinds of significant human health or environmental incidents that's an ongoing program. So, there's -- there's a number of mechanisms, not to mention a company filing an application to add a new use -- there's a number of opportunities to sort of (inaudible) the routine programs that allow us to look into any significant new human health or environmental issue for a chemical regardless of what its schedule is. So, we think we can handle that. Jay.

MR. ELLENBERGER: I think it's interesting to -- to learn that Carolyn hates the DCI process. I think you said -- that's what you meant, Carolyn.

MS. BRICKEY: I've always thought it was an awkward tool --

MR. ELLENBERG: And yet, I think it's the process --

MS. BRICKEY: I never told you that?

MR. ELLENBERGER: No. I don't think so.

(Laughter).

MR. ELLENBERGER: So, I -- I think maybe this is another subject that we put on the off ramp and work on maybe with another worker, but I think it's useful. I -- Beth made a very important point that it is a core piece of the commercially sustainable part of our industry, and that's something that we want to just throw overboard, and Carolyn, I think you referred to OMB in less than glowing terms, and maybe we should invite OMB to help us figure out what the problem is or invite them to, you know, take the off ramp and, you know, stay somewhere in the wilderness. Larry.

MR. ELWORTH: I can't tell you how many times people have offered OMB to take the off ramp.

(Laughter).

MR. ELWORTH: Number one, Julie, thank you for revealing so much of your psyche with that table. I hope it's not a cry for help. Two, if we do have the hearings that Bob's talking about, I'd recommend the agency work through the Caesar salad dressing ingredients first, so you don't have that come up again.

Third, I think it would be really helpful if we had a timeline here, kind of protected timeline of what

people could really look for maybe in a couple of three different scenarios of, you know, for where you could get off this fairly easily, where you're not requiring a whole lot of review, but I haven't been really clear on what the timeline would be from the time the agency would say here you on the schedule of the list and when you might actually expect to be done. I'm not -- I mean, this obviously isn't a hard and fast commitment.

Two other quick things: One is let's assume the rule gets done in 2006, how many chemicals are cued up then? Do you figure it's just going to be 80, or are you going to have, based on what the statute suggests, it would interesting to know, and finally, can you say a little bit more about what you have in mind with the economic analysis?

MR. JONES: I'm trying to remember the order of your questions. There were just actually two questions.

UNIDENTIFIED MALE: Right.

MR. JONES: As far as the scheduling issue, we would -- what we're thinking of on an annual basis, I think as Ray said or one of the other people (inaudible)

what we intend to do for the next 12 months could be sort of a rolling schedule or a calendar year, fiscal year, and you know, we think that as we get into the actual review of chemicals that obviously some are going to be easy to go through fairly quickly, other ones are going to be more complex, cumbersome, take much more time.

So, if our goal is 80 decisions a year, we know that we're going to probably have to really work on more than 80 because some may take more than a year to do. We haven't arrived at exactly what the number is, whether it's 100, 120, but we'll -- we'll work on that and, again, make adjustments as time goes on, but we are trying to -- so we are achieving that 80 decisions a year.

UNIDENTIFIED MALE: So, it's really a scheduling -- to answer that question, you'd have to really think through the scheduling (inaudible) --

MR. JONES: Right. Right. Right.

UNIDENTIFIED MALE: -- to see what it would look like.

MR. JONES: I mean --

UNIDENTIFIED MALE: Okay.

MR. JONES: -- that's sort of like what we do now with new registrations or re-registrations. You put in more in the cue than what you think you're going to get out because of just -- anticipated issues. As far as the economic analysis goes, I -- the kind of information that we believe we will that we will get out of the pilot program, each of those -- each of the kinds of items that we will identify, such as how many -- how many of the pilot chemicals, and if we're doing perhaps 20, 30, 40 pilot chemicals, a fair number to give us a real good sense of what its like -- what its likely to be, each of those things we will tag or identify like new risk assessment, we generally know what that (inaudible) in terms of FTDs and recent contract dollars, for example, or what kind of risk assessment, is it both for human health and the environment or just one of them? Is it just endangered species risk assessment? We have a fairly good sense of what those costs are. Likewise, if we identify a number of the chemicals that have data gaps, well, what are the data gaps, and what kinds of studies are they? Well, we've got individual costs for those. Who knows what those are going to cost, both us,

in terms of reviewing the studies when they come in, as well as industry for generating the studies.

So, each of those items that we would tabulate and report, we have a good sense of the cost, and putting all those together, it gives us a fairly good picture, I think a representative picture of what it's likely to cost. You sort of spread that out over all of the chemicals over a 15 year basis, that's what we would put into our proposed rule. So, you would see that to comment on, and hopefully, you've agreed, disagreed, had other information to provide that to us during the comment period so we could refine that. Steve.

MR. BALLING: Well, you know, I missed the last couple PPDC meetings, and I had told Margie that Larry Elworth could speak for me because we're always one mind. After that Caesar salad comment, I think I'm going to make sure I make the rest of the meetings.

(Laughter).

MR. BALLING: My question is sort of is there a possibility -- is there an opportunity for sort of an early warning system in the context of USDA and the commodity groups doing these pest management strategic

plans and the effort to try to plan forward as much as five-plus years in terms of the research we're trying to do, the kinds of pesticides that there might be issues with, is there a way we can have a sense that this compound or these compounds might be in trouble, and I think that really benefitted us a lot in the FQPA re-registration, reassessment process. When we knew the O.P.s were -- potentially had some issues and we were able to ahead of time look at what our opportunities for, number one, changing what we do, and number two, looking to defend the uses that we currently had.

MS. HAYSON: Steve, one of the things we're considering doing is when we put out our baseline information of what we have on a compound is identify those key issues we think could be troublesome, specifically if we think there's a risk that exceeds -- there's data gaps, or currently, you know, maybe an updated risk assessment is needed and we think there could be real concerns. That, however, would only go sort of for the next year or two.

MR. BALLING: Yeah.

MS. HAYSON: I think your question is -- is

broader, and I think we would continue to with (inaudible) communities as we learn issues on classes of compounds.

MR. JONES: Yeah. There is real value if we could look two to three years out. You know, obviously, you know, what seasonal crop -- cropping situation we -- most of us deal with, and you know, you only get one or two chances to look at those kinds of opportunities to make change.

MR. BALLING: Okay.

MR. JONES: Carol.

MS. STROEBEL: Thank you. In learning more about the process that you're looking at, I just was wondering -- folks in the workgroup had thought -- talked about some of the stakeholder involvement issues for different groups of stakeholders. I can appreciate, for example, that at the beginning of the year you would rather put out one notice about the chemicals you're looking at, which may be 80 or more and that you're going to be looking at them, but for a lot of public interest scientists that doesn't mean that they'll catch that for this one particular AI that they are going to be aware of

the docket comment period because I think in the public interest community people are not going to be able to track this very closely or are not going to expect to comment on everyone, but I think in this process I can understand the balance of not wanting to put out rafts and rafts of Federal Register notices, but I think there would be missed opportunities for some stakeholders to be aware of the process at the right time.

MR. JONES: That's a good point, and I think all the stakeholders, whether its advocacy groups, grower groups, whomever, and I think we're -- we're quite sensitive to that, and so what we've thought of doing is in addition to the -- sort of the annual Federal Register notice or perhaps quarterly we (inaudible) decide that, make sure our schedules are up-to-date on our website, that we will announce schedules also on our list serve and -- and use, you know, other opportunities to let folks know about what is coming up in the next perhaps couple years, next year, the next quarter, and we'll just -- we'll do our best to get the word out, but right, we -- by have -- by opening the e-docket by having this information in -- and again, it's another opportunity

where really all the interested stakeholders can go to look at what -- what's in the agency's files that we're going to be relying on for the risk assessment, what we think the key issues might be that we've got to tackle before we do the registration review for that chemical case or active ingredients and provide -- provide groups the opportunity to add additional information or to suggest to the agency that we also look at some additional issues that we haven't identified.

MS. HAYSON: Dan.

MR. BOTTS: A couple of process issues relative to acceptance of the recommendations of the workgroup and how PPDC's role in that process will be. To officially receive it, don't we have to have a recommendation to accept the recommendations from the work group from the PPDC at some time to move forward, and if that's the case, is there enough meat on the bones from the framework, and having been an unofficial member of this workgroup and participating as a public audience participant at about half the meetings, a lot of the questions and issues that have been raised by people around this table have been discussed ad nauseam within

the workgroup to try to come up with a framework that would attempt to address those issues and give the agency enough guidance from fleshing out around those parameters everything from data quality for stakeholder submissions to what constitutes the appropriate level of concern to trigger a DCI versus when the off ramp works and all these things.

I guess my question to the agency as an interested bystander and also as a member of PPDC, what do you need from us to go forward to get the pilot process started where you're really going to flesh out some of those specific issues that need to be dealt with beyond the timeline to get this rule in place under the framework that you have, and if it takes a motion to accept a recommendation of the workgroup, you can consider just that motion, but some of those issues are going to have to be fleshed out a little further down the road, I think, just after the discussion that you've heard today from the group around the table.

MR. JONES: Let me take that one (inaudible) first, I'll accept your motion that we do need to either have the PPDC endorse the recommendations of this

workgroup or offer an alternative, not endorsing one, one out of three, whatever is your pleasure. I will say that once we have that clarified, I believe we have what we need to do the next step. Assuming those -- those recommendations are accepted, I think we now have the framework or the skeleton for registration review.

We will then take that to our pilot process, and I think that's what is going to put the flesh on those bones, and then I want to chat with you a little bit about the PPDC workgroup participation in that next part, which is the flesh on the bones part.

So, we have a motion to -- your motioning to consider the recommendations, Dan, or accept them?

MR. BOTTS: I would take it one step further than considering. I would make a motion that we accept the recommendations all three of the workgroups has considered this morning.

MR. JONES: Anyone want to second Dan's motion. Dennis? Larry, is your card up for some reason --

MR. ELWORTH: Yeah -- well, no, I just like it there.

(Laughter).

MR. ELWORTH: This will be -- Margie, you have to check in on this. This will be the first time we've actually formally voted to accept a recommendation -- set of recommendations. Which one did we do before, do you remember?

MR. JONES: I don't know that we're going to vote --

UNIDENTIFIED MALE: Going back to 1994, we did section 18s, we did an ecological risk assessment process and a whole --

MR. ELWORTH: No. We didn't do the ecological risk assessment because we couldn't agree on it. That's why I remember that.

(Laughter).

MR. JONES: Actually, the group -- the group has done a number of -- we're not necessarily going to vote now. I --

MR. ELWORTH: Oh, okay. Okay.

MR. JONES: -- but we're going to get a sense of the group, is anyone not on board with --

MR. ELWORTH: Okay. Okay. Okay.

MR. JONES: -- the recommendations, I'd like to

know that.

MR. ELWORTH: Okay. Okay. I was just trying to figure out if we'd ever actually done that or not.

MR. JONES: Yes, we have a number of times.

MR. ELWORTH: Okay. Okay.

MR. JONES: Julie.

MS. SPAGNOLI: Just to ans -- I'm thinking the last meeting when the work group presented its first group of recommendations, the recommendations of the committee was for the workgroup to continue their work, and that's really what we've -- we've done here, and I think what we're looking for now is, I think, as they've said, we've kind of put a framework together, and I think in looking to say, okay, here's kind of what we would see is the next step forward, which is the pilot process, and I think that's maybe what we're looking for from the committee. It should be take those next steps forward based on this framework.

MR. JONES: Is there anyone who wants to voice any objection over any aspect of the recommendations before -- I will say that the agency is very inclined to accept the recommendations, if they are recommendations,

and even if they're not, I think that they've given us the sense of what the framework is going to look like, but it would be useful to know if there is anyone or any group that has some issue with any aspect of them before we -- okay. Well, I will consider those recommendations to be from the PPDC to the agency. Very good.

Okay. Well, the -- the next case that I think is worth talking a little bit about -- and we have not yet figured out precisely how we would like the PPDC workgroups to continue in this effect, and we need to do a little work on that end, but as you've heard, our next step is this pilot process where I view it very much as, you know, you can either call it the rubber hitting the road, the flesh on the bones. In some ways the work that all of you have done where there's been a lot of consensus has been not easy, but it's easy to agree without knowing there may be differences, I'll say it that way.

When we start actually looking at a chemical and saying, okay, here's where we'd make the off ramp, and we're not going to know it when we see it, but we're certainly going to show it when we see it --

(Laughter).

MR. JONES: -- and that is where I think there can -- there can be a lot of dialogue, discussion, the potential for disagreement gets higher, but I'm quite certain that unless we show our work in that area, we have no real chance of getting a rule out under the schedule that we've got. What slows down rule-making is a lot of dissension, disagreement. Carolyn.

MS. BRICKEY: Yeah. When would you anticipate coming back to this group with a pilot? Do you think it will be done in six months or --

MR. JONES: Yeah, actually before then.

MS. BRICKEY: -- four months?

MR. JONES: It will be before that. I -- I'll see that the -- there will be -- before we get back together again that the PPDC workgroup will have met at least once to have gotten a sense of what our pilot is showing, and we'll need to -- we'll need to -- again, we'll need to think about how to tee that up in a way that's effective, efficient; although, it may involve a fair amount of time from the membership. If you really want to sort of look at how we -- we, in this pilot

process, make choices, it's -- I think it will be somewhat time-consuming, really, you know, a whole day spent on it.

So, yeah, I think our schedule is rather ambitious in that sense, and I'm pretty confident we'll be able to at least have one meeting of the subgroup, and that will really give you a sense and will really give us a sense of where you're coming from, and you'll really understand how -- what the words you just heard meant and how we're actually putting them into -- would propose to put them into practice. Sense of the group? Oh, I'm sorry, Dan.

MR. BOTTS: Just one follow-up in regard to the workgroup process and the pilot program is there. A lot of the initial workgroup members -- and it's not a requirement that people on a workgroup be actual members of PPDC or PPDC members prior to this reconstitution. Are you going to put a whole new group together? Are you assuming that this same workgroup is going to be involved in the pilot process? Are you going to take volunteers today to participate in that? If you're looking at a 60 to 90 window, it's going to mean an awful lot of time

commitment from somebody to be participating, be involved?

MR. JONES: I would assume the existing group will be -- continued to be constituted in its current form. If there are other members of the PPDC who haven't been on it or haven't been active in it and want to be, I think we would be certainly definitely open to that new engagement. Yeah, Bob.

MR. ROSENBERG: Just one thing about the workgroup process, as the process evolved and became more significant, it became, I think, probably registrant driven and commodity groups, user groups, and folks like that probably didn't have a whole lot to offer, but in this next little period of time as the work group deliberates, I think it would be useful to sort of re-engage some of the commodity groups, farm groups, non-ag user groups in specifically the public participation component, something that I think we do have something to say about.

MR. JONES: We -- we -- that's a point well-taken. I would just recharacterize it a little bit. We, I think, have done everything we can, including calling

many of you to say you need to be there because we don't have -- we don't have the diversity of stakeholders in this process, and we'll continue to do that, but it really is up to, individually and collectively, you to participate when an opportunity's been given, and if you've got issues of were not giving you enough time, get us -- get us that. Feed that back, and we'll make sure we're giving you enough time, but I think we've been pretty aggressive in our outreach to people who have already signed up, but it's very important to have broad stakeholder participation not only at this meeting but in working groups leading up to these meetings, and we'll continue to work hard to achieve that. Sue and then Larry.

MS. HAYSON: Oh, I just wanted to say that it did -- the group did kind of whittle down because, unbelievably, there are people who do not find the nuts and bolts of registration particularly interesting.

(Laughter).

MS. HAYSON: It's really shocking, but on the other hand, I think that Bob is right, I think as the pilot proceeds and there are actual product, at least,

you know, in the process of becoming a product, I think it's really going to be maybe even more interesting than the second phase. So --

MR. JONES: Yeah. I would agree that you'll really be able to determine what did the agency -- how is the agency interpreting early off, how is the agency going to actually make choice about we need a piece of data that we don't have and we're going to have to ask for it. How is the agency going to decide whether the -- the most recent assessment (inaudible), but those things are important and interesting to you, which I think it is to everyone around this table, I think it would be -- you would benefit and we would, most importantly, benefit from your participation in that part of the exercise. Larry.

MR. ELWORTH: Well, that -- just to follow up on those two comments, it would be -- it would probably be useful to try to, within the overall pilot thing, pilot different ways of going about that kind of stakeholder involvement, figuring out how to cue up issues for people that you can anticipate and look at that as really a sub-component of this because that's going to be pretty

critical, but also it's going to be really challenging if you're doing potentially somewhere between 80 and 120 re-registration -- registration review issues kind of at once. Doing that is going to be a little bit of a challenge for you, as well.

MR. JONES: All right. Well, I think we have a pretty clearly defined next step. Thanks to the PPDC workgroup, and thanks Jay and Susan. We are going to take a break right now, and I'm very hopeful that our audio issue is going to be resolved and there won't be so much background noise. Thanks. Be back at five-of.

(Whereupon, a brief recess was taken.)

UNIDENTIFIED MALE: Excuse me, everybody. Listen, I just want to make -- share with you there was a speaker problem on the ceiling. We've taken care of it. What we're going to ask everybody since we're doing the recording is that they would speak in the direction of the microphone. If they need to move a microphone closer, they can do that. You need to be directional. So, you have to talk to the mikes; okay? And we'll be there for you. Thank you for your patience.

MR. JONES: Talk to the mike. Hey, Margie, would you go to the corridor and see if you can rally some of the troops? I need pineapple, is what I need. This is a vacation, I think.

(Informal conversation).

MR. JONES: Okay. The next topic, and we brought this topic to the PPDC at our last meeting last October or thereabouts, and I got the distinct impression that for -- for whatever reason, the committee was not quite able to get its arms around the issue, and that could be for a lot of reasons. It's somewhat of a dense topic. There is a fair amount of information to convey to -- for you to have an appreciation for what the globally harmonized system is about, and it may have also seemed a little bit off in the distance to you, but I think that it's a fair characterization to say that -- that every group represented in this room has a stake in the policy choices and the implementation of this -- this program, and so I -- we thought it was important to come back and take another stab at engaging this group, and so Mary Francis Lowe (phonetic) and Debbie McCall (phonetic) are going to give somewhat of a detailed briefing around

the globally harmonized system, what our plans are, and we'll end with a couple of questions that we have for all of you that we're looking for some feedback on. With that, Mary Francis?

MS. LOWE: Good morning. As you recall, Debbie and I are co-chairing and internal OPPTS working group that also includes representatives of all of the OPP divisions, OCIA, OGC, OPPT, a couple of state representatives from New York and California, and also a pesticide educator, Candice Barthalomew, from Connecticut.

So, what we're going to talk about this morning are the initial recommendations of that group, and we thought we'd start with just something to grab people's attention, you know, why should we care about this? Well, we think that implementation of GHS is likely to affect all pesticide labels, and obviously that means that every pesticide user and handler will need to be able to read and understand the new label.

So, today we thought we'd review very briefly some of the things we talked about last time about what the GHS is, then get into a preview of our plans and

initial recommendations and get some input on those. We do expect to issue a formal request for stakeholder input in the coming weeks.

So, what is the GHS? It's a common and coherent approach to defining and classifying chemical hazards and communicating hazard information on labels and safety data sheets. The target audiences, again, are workers, consumers, transport workers, emergency responders, and the idea is that it would be the underlying infrastructure, sort of step one, particularly for developing countries in having sound management of chemicals policies. It got its big push internationally at the U.N. conference on environment and development, known as the Rio or Earth Summit in 1992.

The negotiations went on for over a decade. They were tripartite negotiations, meaning that they involve not only Government representatives but also industry representatives and other stakeholder groups. The principal stakeholder groups from the U.S. that were involved were the labor unions representing workers in the chemical industry. Those negotiations were completed in December 2002, and then the final blessing of the

system at the international level by the U.N. economic and social council happened in July 2003. So, now at the international level, they think, okay, here it is. Countries can go ahead and do it.

The scope of the GHS is quite broad. It goes beyond pesticides. It's based on harmonizing existing systems for chemicals in transport, in the workplace, consumer products and pesticides, and a basic guiding principle of the whole effort was that this would be done without lowering the protection of existing systems, and that was something that you will see accounts for there are some areas where we moved to things that we don't now do from a U.S. perspective not only to harmonize with other countries but also to harmonize within the U.S. We have the department of transportation, the consumer product safety commission, the occupational safety and health administration, and EPA, and we all have somewhat different systems. So, one of the benefits should be to harmonize internally.

Classification is based on intrinsic properties or hazards. It's not designed to harmonize risk assessment or risk management. As I mentioned, it covers

all chemicals with the caveat that it doesn't cover things like pesticide residues in food, or food additives in food, or cosmetics in what we call the consumer use setting. Those same chemicals, though, would be covered in the workplace and in transport, and that is consistent with the U.S. regulatory framework, and just this is our last review slide, the goals are to promote safer handling, transport, and use of chemicals Worldwide and at the same time, to facilitate international trade by promoting greater consistency in the regulatory requirements that manufacturers and shippers face. We also think that it should reduce the need for testing, in some cases because there won't be the need to test to deal with multiple requirements, and then, as I mentioned, to assist developing countries, in particular, in initiating chemical regulatory programs if they don't have anything to start with. So, now we look at what -- what does -- what needs to be harmonized for something to be -- a system to be consistent with the GHS.

The GHS contains classification criteria for physical hazards, for all health hazards, and one environmental hazard, aquatic toxicity, and then based on

the classification, there are certain standardized label elements that would be triggered by the GHS: Hazard pictograms, which are a symbol in a red diamond border, use of just two signal words, danger and warning only, and then hazard statements for each hazard class and category.

So, the hazard class would be, for example, acute toxicity, and then it would be category one, two, three, four, and five. I put product identifiers and precautionary statements in brackets because the GHS says you should have product and supplier identifiers on the label and gives you some guidance about what that means but does not try to standardize them.

Similarly, one of the annexes gives sample precautionary statements, but those are not yet standardized. For those of you who would like to take a look at it, the U.N. website now has a paper on there prepared by Germany which proposes some ideas to try to promote more harmonization of precautionary statements in the -- in the future, and then final, format and contents for safety data sheets are standardized in the GHS, but perhaps just as important to those of us in pesticide

were the things that don't need to change to be consistent with the GHS, that includes supplemental information, that's additional information the label. We require a lot more than pictograms, signal words, and hazard statements on our labels, and we think the other stuff's important, too, obviously.

It's completely consistent with the GHS to have that supplemental information as long as it doesn't contradict or detract from the GHS information. Testing methods and data requirements, officially the GHS is testing in test method neutral. Some programs like pesticides can and do require data that's acknowledged in the GHS. Other regulatory programs don't have that authority, and so they're trying to use, you know, the best data they can get.

So, the testing methods are also not prescribed for health and environmental hazards. They are prescribed for physical hazards, however. Something that was important to our Consumer Product Safety Commission is what we call risk-based labeling for consumer products in the consumer use setting. This is an option under the GHS, and it's an option that's in there largely at the

U.S.'s assistance, and the idea being that for CPSC regulated products, in particular, if you're looking at chronic effects, you can make certain protective assumptions in accordance with the policies of the regulatory agencies, and if you conclude that exposure would be minimal that might mean that the hazard would not be on the label, but if the risk analysis leads you to conclude that the hazards should be on the label, then to be consistent with GHS, you should use the GHS label elements.

Another thing that doesn't need to change is the scope of hazards that are covered by various systems. You don't have to pick up every hazard class in the GHS to be considered consistent with the GHS, and probably the most dramatic or most often cited example of that is the transportation system focuses now on physical hazards and the most severe classes of acute toxicity, and they would not need to pick other hazards in order to be considered consistent with the GHS, but if they did decide, for example, and there's a good chance they will, to start labeling in some way for aquatic toxicity, then to be consistent with the GHS, they should pick up the

classification criteria and the label elements, and then finally downstream effects, or you might call those risk management measures, if there are things that are now tied to hazard classification beyond hazard communication, those links don't need to be maintained with the new categories if they don't make sense any longer. So, countries have a reason to reexamine those linkages, see if they want to maintain them or change them because we, again, weren't trying to harmonize risk management but hazard communication.

This is probably more of an issue for some of the OCIA regulated things. OCIA is very much based on --

(Tape 2, Side B.)

MS. LOWE: -- regardless of the level of risk in terms of the label and the safety data sheet, but obviously the risk management measures depend on exposure and further analysis.

So, when our internal working group got together we went through the GHS. We did some comparisons, obviously, of our current practices. Of course, we've been doing that all along, but now that the system was complete, we needed to step back and take a look at it as

a whole, and we basically had these three general guiding rules for our approach and our initial recommendations for implementing the GHS for pesticides. The first was to cover all pesticides alike. Technically, the GHS only applies to chemicals, but our groups feeling that -- was that it probably made the most sense to treat everything that's called a pesticide under (inaudible) for the same way for the purposes of the GHS. Obviously, if they don't meet the hazard criteria, some kinds of pesticides just won't be classified as being -- as having that hazard.

We decided that our initial inclination was to adopt the GHS for all the hazard classes for which we now label. That's the building-block issue, and I'll get back to that in the next slide, and then finally, in general, the GHS has a lot of things in there that we don't now do that we might decide to do at some point or we could decide to do, and our initial recommendation is let's limit the changes to what we need to do to be consistent with the GHS, that that is a big enough task in and of itself.

So, here is the first comparison of the building

blocks that are in the GHS and whether they're covered by the Office of Pesticide Programs and the Canadian Pest Management regulatory agency. So, you see, we all cover acute toxicity, skin and eye corrosion, irritation, skin sensitization.

We don't cover germ cell mutigenicity as it's defined in the GHS or carcinogenicity, reproductive toxicity. We have a limited exception to this TOST category, TOST is target organ systemic toxicity, and basically it's any health hazard that isn't covered by one of the other categories. So, the target organ might be kidney damage, or liver damage, neurotoxicity, and so forth. That -- that is what is T-O-S-T on this chart.

And then finally, aquatic toxicity, we do cover it for -- but right now our -- the limit of our coverage and our rules is the equivalent of the GHS category one for acute aquatic toxicity. So, we'll walk through some of our initial recommendations on various hazard classes in the GHS and highlight, in particular, the areas where we might have some flexibility in what -- what we would do and what our initial recommendation is to do. GHS has five categories for acute toxicity lethality, five

categories each for oral, dermal, and inhalation toxicity. We currently have four. So, we would move to the GHS, five categories. Category five does have an upper limit; although, there's always an escape clause that if -- even if it has an LD 50 or acute toxicity level that is above the cut-off, if there's any information indicating a concern at that level, then it should be on the label. The word "poison" is not part of the globally harmonized system. It's one of the few things that is actually specified in our statute.

Our feeling is that poison is one of those things that qualifies as supplemental information. It doesn't detract from the DHS signal word of danger, it actually reemphasizes it, and so we would keep it for categories one and two.

Categories one and two of the GHS are equivalent to OPP's current category one. So, there wouldn't be any change in the products to which the word poison would apply. Skin and eye irritation and corrosion, we were pretty similar to the GHS. There was one area where it wasn't immediately clear what should be done. The lowest level of eye irritation in the GHS is mildly irritating,

affects, clearing within seven days.

We have an even more mild category, which is minimal effects, clearing within 24 hours. Obviously, if it clears in 24 hours, it clears in seven days, but you know, do we want to somehow maintain that -- that lowest level?

That lowest level does not now automatically trigger any label warnings in the OPP system. It's the registrant's option if they want to put the category three label information. So, we weren't really sure what was the best way to go, and so our initial thinking was that we could continue to make that an optional thing for the registrant, but the -- the option would be either no labeling, which is what they could do now, or the lowest level GHS labeling, which is the 2B, which would include a "warning, causes eye irritation" statement. It would not include a symbol.

Skin sensitization, we're essentially equivalent. You either a sensitizer or you aren't -- or you aren't. There is some interest in the future of trying to distinguish between strong and weak sensitizers, but the feeling at the time of the

negotiation was that the -- the testing methodologies and so forth were just not there to enable that distinction. So, the only question here is that there was a difference in our hazard statement. Ours is a bit longer and emphasizes prolonged and repeated contact. The GHS has a more simply "may cause allergic" or "causes allergic skin reaction" and our feeling was we could go with that statement.

If we felt like we needed it later, we could add some more supplemental information but that that statement was clear and would be useful to the people using the products, and then the final GHS category that we -- our hazard class that we now cover is aquatic toxicity.

As I mentioned, current rules only cover acute aquatic toxicity category one. Our working group, largely based on the recommendations of our environmental effects and -- environment (inaudible) and effects division is recommending that we accept the GHS acute tox categories one to three and adopt all the GHS label elements, which would include on the highest level of toxicity, the use of the signal word warning, and right

now OPP does not permit environmental effects to have a signal word. So, this is a new thing for us.

Flammability and physical hazards: I realize that we may need to explore this in more detail in the future with our colleagues in the Department of Transportation. They had the U.S. lead for negotiations on the physical hazards, but our initial recommendation is that we would pick up all of the GHS classed and categories. Now, again, if you don't meet the classification criteria, you're not classified and nothing goes on your label. So, that doesn't mean that, you know, there's going to be new symbols and so forth on products that don't have those characteristics, and again, right now we don't allow signal words on physical hazards like flammability, and we decided we could agree to allow, for example, danger on highly -- highly flammable substances, that that would be helpful and not -- not misleading. Product identifier, we looked at our current requirements, read them in the light of the GHS, and we really feel that they're consistent that we can say that what we do now satisfied the GHS consistency rule for product identifier. The disclosure rules for

inert ingredients are somewhat different in that the GHS says that you should disclose all of the ingredients that contribute to classification of the chemical. However, it also provides that confidential business information rules adopted at the national level would take precedence over that, and one thing to stress is that it's not that the hazard doesn't need to be disclosed, it's that the ingredient doesn't need to be disclosed. The hazard would have to be disclosed on the product.

Supplier identifiers: Again, we think our current requirements satisfy -- this is all -- it's not a surprise that we're close because, after all, we were part of the negotiation, but there is one area where the GHS says that you ought to have a phone number, and OPP currently strongly encourages a phone number, and a lot of products have it, but it's not an absolute requirement, and that's -- that's another area where we'll be exploring through the public comment process. So, that's essentially the building blocks of the GHS that we're initially recommending that we pick up for the pesticide program. Then we turn to looking at, well, what it is going to mean in terms of impact on our

divisions and on our stakeholders?

And this first slide gives you some clue of the universe. There are over 22,000 labels when we took this snapshot through the data systems. The majority -- not quite the majority but the largest number, of course they're in the registration division, number in the special review and re-registration division, the antimicrobial division, and the bio-pesticides and pollution prevention division, but the registering divisions are not the only divisions that will be affected by trying to implement the GHS. Our information systems, our front end process staff will obviously be impacted as label changes come in. My division, the field and external affairs division and also the biological effects and analysis division will need to be involved in rule-making and rule-making analyses, also planning, communications, outreach.

There are certain elements in our worker protection standard that are currently linked to hazard classification, and so we'll need to make sure that any links we have there are what we want them to be and so forth.

So, kinds of work our group needs to do in the future: In addition to doing things like reviewing the new paper on precautionary statements to try to guide the international work to be something that we could live with or is consistent with what we do, we haven't gotten into the detail of developing label specifications, and on size and placement, there is some guidance in the annexes to the GHS documents, but the GHS is not prescriptive. It's not a model regulation. So, it doesn't do things like specify point sizes or -- or anything like that.

We -- also, we're looking at, well, how would we actually go about implementing this for these 22,000-plus labels, and so what our current plan is is that we have developed what we are calling a white paper that has these recommendations, as well as the background of how the GHS was developed and a comparison of our current system with the GHS. That's current in draft, and we are hoping to be able to put that out fairly soon. We would put that out with a notice of availability for public comment, and I will get to the process a little bit more.

We feel that we are going to need to do rule-

making to change, most notably, part 156, our basic labeling rules, but we are also coming through with our Office of General Counsel, other regulations that might be linked to hazard classification labeling to see what changes, if any, may be appropriate there.

The actual, physical way of implementing the GHS: One thought was we could make it a separate approval process, perhaps with contract support, set deadlines for when we'd like certain kinds of labels or classes of chemical to come in with their labels, review them, and so forth. That has some advantages, but it also have the disadvantage of creating a major, new workload for ourselves and for our stakeholders. The second possibility we were considering is what we've been calling the routine business model, which would, you know, when we have the rules change and we finalize our recommendations of what we want to do to implement the GHS, ask registrants that for the next two years or however length of time, whenever you want to propose a label change, when you send that in, we would like to see the GHS label changes sent in at the same time. So, it's something that could be folded into routine business planning.

Finally, resources are going to be an issue for us, and we're -- we're thinking that some of the streamlining or efficiencies that our program is able to achieve based on the new fee legislation may actually be helpful to us in GHS, as well. It's not that the -- I realize this might be a little misleading. We're not talking about linking the GHS to the fee legislation but just that those kinds of overall improvements could help us review labels that come in for -- for GHS, as well.

So, next steps, again, when we talked last time, one of the things we emphasized is that we really do want to try to have a North American coordinated approach to this. Of course, we'd like to coordinate with the whole world, but we'll -- we want to start with our NAFTA partners, and it was included in the NAFTA five year strategy that was adopted a year or so ago that we would strive for coordinated GHS implementation.

So, we are sharing these initial recommendations. I think this group is the first that gets this presentation, but we will also be sharing with -- with Canada and discussing with Canada and Mexico. It is on the agenda for the executive board meeting, I guess it's

June 3rd and 4th, coming up. So, that's when the initial substantive discussions may begin with them, and based on how those things go, as I said, our plan would be that we would publish a notice of availability of our initial paper and get public input on that, perhaps do a public meeting. There is also some talk about -- it's more than just talk -- I mentioned that OCIA, DOT, and the Consumer Product Safety Commission will also need to do things to implement the GHS. So, we have an interagency group, and we're discussing possibilities for U.S. Government-wide event or action.

So, the next two slides are really international implementation considerations: When is it supposed to be done, and how are we obligated? The GHS is a voluntary international agreement, and by that we mean it does not impose binding treaty obligation on countries under international law. So, it doesn't require Senate ratification or anything like that. However, we want to be very clear that the intent has been all along that although the GHS is not legally binding on countries, obviously to the extent that regulatory programs change their requirements, those changes become binding on the

regulatory -- regulated universe. So, it's not voluntary in the sense of the regulated community once the regulatory agencies change their rules. The idea all along was that countries with existing systems like the U.S. would harmonize them to be consistent with the GHS and that the GHS could be the fundamental basis for countries that don't have well-developed regulatory systems to be able to build them.

Timing: We don't have an international implementation schedule, and I think the people involved in the international discussions are somewhat schizoid on this issue. On the one hand, they would like everything to be done in a coordinated fashion. On the other hand, none of us feel we can commit to a firm schedule of step-by-step events. So, it's likely to be incremental.

The inter-Governmental form on chemical safety and the World Summit on the sustainable developments set an overall goal of 2008 for implementation. The Asia-Pacific Economic Cooperation Forum set a more ambitious goal, encouraging implementation by 2006. The U.S., and Canada, and Mexico are all members of APEC, by the way.

From a pesticide perspective, we always like to

point out that different systems and sectors might take different time frames, and since we're the only major program that actually reviews the actual labels, you know, we feel we deserve some consideration in that, and of course, any implementation, we'll need to consider steps to have a transition so that things aren't disrupted.

So, we'll go back and stop here. We've identified basically the -- the key issues for consideration that we discussed in our -- our group and we will be seeking input on is, first of all, the scope of applications in GHS. These are the general rules that guided our thinking: That we would limit our initial implementation activities to what we need to do to be consistent with the GHS, having participated in those negotiations for a number of years, that we would cover all pesticides alike, using the (inaudible) definition, even if some of them are technically not -- not chemicals, and that we would adopt the GHS hazards and building blocks for the hazard classes that we now cover or the effects that we now cover.

Second major area is how to actually handle the submission and review process for labels that are changed

to be consistent with the GHS, and I mentioned the two basic options, which are a separate approval process or folding it into routine submissions that -- that come into the program, and then finally, get back to who needs to know about the GHS, we are going to need a lot of help on outreach and education strategies to get input and then to educate people about what the new labels mean. So, those are, I think, the three major areas where we're looking for input.

Any -- any -- any comments?

UNIDENTIFIED MALE: (Inaudible).

UNIDENTIFIED FEMALE: I do have a comment.

MS. LOWE: Staring at your face, not your card.

UNIDENTIFIED FEMALE: Very (inaudible) statement there and pretty much your very first one that this will cover all pesticides, not just restricted use pesticides and that you're going to be relying on lots of outside help for effective outreach and education strategies, and I'm -- I'm very glad to hear that you are utilizing Candice Bartholomew, one of our pesticide safety education program coordinators to help in this effort, but -- sorry -- but it's interesting because right now we are in the

middle of the second year of a very drastic cut in funds for pesticide safety education programs across the country, and states are in the very process of dismantling their programs.

What's likely to go first is personnel to do the job who have the history, who understand what the old labels meant and what the new labels will mean, and what's also likely to go next is those outreach programs that we already have established for non-programs -- not restricted use pesticide programs.

We will probably try our very, very best to continue those; although, we are shutting down some of those in some states because we just don't have the resources to do it, but how we're going to continue to do it for our non-rup (phonetic) users, I really don't see, and I think that we are your best outreach group across the country that already has these ties.

So, we certainly want to help. We've had Candice involved. We've been working -- as soon as began to hear about GHS, we said we wanted to help on this, but it's going to be a very, very confusing system. There are a lot of changes. If you really want to do risk

communication, people need to understand what the new labels will mean, and EPA will really have to recognize that the cuts in the -- that were made the pesticide safety education program funding will have drastic implications for helping to do this work.

UNIDENTIFIED MALE: I had a follow-up question about the hazard classes on labeling. From the Farm Worker community, we very much welcome finally getting on the label the chronic effects but trying to make heads or tails out of what is that going to look like in terms of, as I understand it, there is going to be five categories; is that right, and so is the category going to be kind of the aggregate sum of the risk of both acute and chronic, or is it going to be separated and out, and then the follow-up question to that is especially on the chronic, what data is that going to be based upon and submitted to what agency?

MS. LOWE: As far as pesticides are concerned, as I said, we were operating on the premiss that we would limit the changes that we make to our current labels to those that we need to do to be consistent with the GHS.

That would not include labeling for chronic

effects. We expect OCIA to pick up the chronic effects for their workplace (inaudible) programs, but we are not now considering doing that. More generally, the five categories -- maybe to back up -- and the GHS document is available on the -- on the web, and this will be in our paper when we -- when we put it out there, as well.

The hazard class is acute toxicity, and within that, there are five categories. The first category is an LD 50 or acute tox estimate of five milligrams per kilogram or less oral, for example. Actually, we have a -- we have the slide.

UNIDENTIFIED FEMALE: Slide 27, slide 27.

MS. LOWE: Twenty-seven, this shows you the --

UNIDENTIFIED FEMALE: Twenty-six.

MS. LOWE: No, it's 28. We have a few extra ones just in case some questions come up. These are the GHS classification criteria for acute toxicity, oral, dermal, inhalation, gas, vapors, dust, and mists. So, the five categories are within the hazard class acute toxicity. Other classes may only have one category. Skin sensitization only has one. It's either sensitized or it isn't. The -- in terms of based on what data, the GHS, as

I mentioned, is data -- is neutral in terms of data requirements or test methods other than the specify that you should use the best available data and internationally recognized methods and so forth. For programs like ours, we have data requirements, and we would anticipate continuing to implement those data requirements unless there's a good scientific reason to do something differently in the future.

So, it would be the data submitted to EPA, and EPA would review the label and decide if we agree with any proposed change in classification the manufacturer might come up with, but the GHS is designed to meet the needs of other systems that aren't as, at least I like to think of, as fortunate as we are or aren't as data-rich as we are, and they don't have the ability to require data, and it's designed to allow self-classification consistent with those programs.

People don't submit labels or safety data sheets to OCIA. They self-classify, and then OCIA can do inspections and decide whether or not they agree with it and take enforcement action later.

So, the GHS is based on satisfying the needs of

all those system, but for us, again, using the premiss that we're limiting changes to what we need to do to be consistent with the GHS, we're not talking about changing our data requirements as a part of this.

UNIDENTIFIED MALE: Just a quick follow-up, as I understood from the presentation that GHS does call for the chronic labeling, so why isn't EPA doing that?

MS. LOWE: It's a building -- it's part of a building block approach that -- just like the DOT is not likely to pick up chronic effects -- in fact, they've announced that probably their changes will be in the area of aquatic toxicity and flammability. They don't cover irritation or things like that. You don't need to pick up every hazard class in the GHS in order to be considered consistent.

They are there for the use of all the regulatory programs. So, programs don't have to pick up every hazard class in order to be considered consistent. If you do choose to label for that hazard class, though, you should use the GHS criteria and label elements. Julie.

MS. SPAGNOLI: I guess the -- the real concern I see here is implementation, and I know that's -- I'm sure

that's what the agency's struggling with, too, as far as options for either blanket submission or business as usual, and I guess from the standpoint of -- of registrants, I think this business as usual type of a model, the disadvantage there is, of course, those registrants who come in with new registrations or because they've proposed a new use or have some other changes may actually end up at a competitive disadvantage to a product that elects not to change their label for whatever reason and especially because you are introducing new categories of hazard warnings, you know, such as if it's going to say danger, flammable, you could have two products on the shelf, one says danger, flammable, and the other could be equivalent and not saying anything at all because it's no longer required. So, I think there's a -- I just can see a very -- especially in the consumer market, a very difficult situation with trying to do the business as usual model because some labels just don't get changed for years, but again, I also see that trying to do all the labels at once is an incredible resource challenge and also that, I mean, while this actually required to go back and review data because the classifications are changing.

I mean, and is there maybe some options for self-certification, you know, with some compliance date in the self-certification and then registration review, or you know, maybe a mechanism to ensure that it's correct, but I -- I just see that, you know, waiting for labels to come in is going to create a very chaotic and unlevel playing-field in the market.

UNIDENTIFIED FEMALE: We are going to need to struggle with the idea of balance that equity, competitive advantage/disadvantage with the resource and workload. So, it's going to be tough.

MR. JONES: Allen --

MS. LOWE: Oh, Allen.

MR. JENNINGS: Thanks. I'm -- maybe I'm getting ahead of the game here, and we will hear about this this afternoon, but I'm wondering if the environmental and aquatic toxicity element will open a back door to environmental marketing claims?

MS. LOWE: Well, it wouldn't have to because the GHS doesn't -- the GHS only has hazard statements. It doesn't have positive statements. So the difference would be that one product might have a hazard statement, and the

other product would have no statement. So, to be consistent with the GHS, we don't need to do anything that would start to permit that. Sue.

MS. HAYSON: Just to follow-up on Julie's point and add another wrinkle to it, at the same time that you will be changing pesticide labels to conform to the GHS, for those exact same products there will also be OCIA involved in changing the MSDSs, and I don't know if you spent any time considering, you know, what kind of coordination would occur there, but you know, the possibility is that depending on what the requirements are, you could have inconsistencies between those two documents, the pesticide label and the MSDS.

MS. LOWE: Well, OCIA has not only been very active in this, someone from OCIA actually chaired the group that was charged with managing the development of the GHS and is our principal representative to the U.N. Committee, and I'm the alternate.

So, we have been working together over the years. OCIA's web page is in connection with hazard communication, in general. It has a lot about GHS on it, including their current comparison of what they're doing

now versus the GHS.

So, we will do our best to coordinate with them and also with the consumer product safety commission and to the extent that there is overlap with DOT, we need to --

MS. HAYSON: Right. DOT is the other --

MS. LOWE: Yeah.

MS. HAYSON: -- yeah, clearly.

MS. LOWE: So, that's something's that recognized. I mean, one advantage that we see to this is that we should have more harmonization within the U.S., not just internationally but within.

UNIDENTIFIED FEMALE: Dr. Ogden.

MS. OGDEN: Yes. I have a quick question for you, will this data be based upon a specific species that should reflect human exposure, or what would it reflect? Would you select one particular animal model, or how are you planning on going about that when you categorize all these pesticides --

MS. LOWE: Well --

MS. OGDEN: -- (inaudible).

MS. LOWE: -- I think you'd have to look at the

actual text to the GHS because the chapters vary in what they say about animal models and what they say about non-animal testing. For example, in the irritation corrosion chapter, it goes through a tiered system, you know, beginning with things like PH values, and you can stop there for some, through in vitro tests and into different types of animal tests that, in general, the GHS attempts for the health and environmental effects not to be terribly specific because we wanted to allow for testing methodologies to evolve over time. So, we don't specify a particular test method except for the physical hazards. Flashpoints and things like that are specified.

MS. OGDEN: Okay. That can -- I mean, I can understand that. However, when you consider a range of 20 to 300 milligrams per kilogram difference -- let's say you had a compound containing -- a chemical containing arcinicals (phonetic) where there is a wide variation in the data, how would you evaluate that?

MS. LOWE: I think in terms of pesticides, and Debbie's probably more expert -- we do what we do now. We'd ask for the data that we think are most appropriate and -- and pick up on the model that we think is most

appropriate for that kind of chemical.

MS. EDWARDS: We have data specific. So, I mean, for -- for every pesticide product, there is data specific to that pesticide product. So, it's not a range of information on a particular kind of -- or class of compound. It's actually very specific for that product, does that answer your question?

MS. OGDEN: Yes. That's fine.

MS. LOWE: Patti.

MS. BRIGHT: Yes. I just had a question regarding the hazard labeling. You have aquatic toxicity on the table, and then someplace else you can refer to it as an environmental/aquatic toxicity. Is this going to be specific for aquatic toxicity?

MS. LOWE: It is -- right now the only environmental hazard class is aquatic toxicity. The thinking is that perhaps in the future there might be another environmental hazard class like terrestrial toxicity.

At the time this was being negotiated, there didn't seem to be enough consensus on how to develop criteria for terrestrial toxicity, but there -- so there's

nothing in the current system. The thought is in the future, there might be.

UNIDENTIFIED FEMALE: It seems to me, as you mentioned, the goal here is really to be able to help guide other countries that don't have -- that are not data rich, and particularly in those countries, wildlife concerns -- wildlife often are an economic resource, particularly pollinators.

So, to ignore that in the hazards really seems like an error because I think that's really something that needs -- I can understand why that would be contentious among the group, but I really think it's something that you guys need to go back and address.

MS. LOWE: I think it's not a matter of ignoring it. I think people, at least from the U.S. perspective, wanted to do it, but nobody else wanted to do it just our way. So -- and I'm -- I'm only half-joking about that because it's just a matter of we're going to continue to do it in our program, but -- and I think the science has advanced somewhat since this -- this all began, but trying to get people -- people's arms around or whatever you want to say, what the criteria ought to be that wouldn't

exclude things that would be important to us was just something that people felt they couldn't -- couldn't reach agreement on at that time, but there is still some -- some interest in pursuing that in the future. So, it's not ignored --

UNIDENTIFIED FEMALE: When you say "in the future" are you talking 15, 20 years in the future, or are you talking --

MS. LOWE: Given that this took over 10 years, I don't know what to say, but I mean, there have been papers filed about it. There have been expert discussions ongoing, and in fact, if -- if you check out the U.N. website, you can see some of the proposals that -- well, they aren't quite proposals yet, but you can read any reports about the discussions that have gone on. So, it's actually being talked about even now, but when it will be ready to actually come to fruition -- I mean, some of the things are do you focus on studies in earthworms? Do you cover, you know, as you say, bees? Do you cover mammals? You know, just -- I'm not the expert, but they assured me that it's terribly complex, and so it's not tomorrow --

UNIDENTIFIED FEMALE: Okay. Thanks.

MS. LOWE: -- but I hope it's not 15 or 20 years.

UNIDENTIFIED FEMALE: Amy.

MS. BROWN: I have a follow-up to Erik's question. It's not clear to me what the EPA's reasoning was behind not putting the chronic hazards on the label and so I'm curious about your reasoning, and then I also want to know by opting not to put those on the label, how are you being consistent with DHS?

MS. EDWARDS: In the workgroup when we were talking about the chronic effects, we started looking at how we actually do our risk management decisions now, and our risk management decisions are -- are based -- how we do our risk assessments, we are pretty confident that the chronic effect that may occur in any given -- with any given chemical class, by the way that we're regulating that chemical, that that chronic effect wouldn't occur.

So, everyone in the workgroup was saying, well, there would only be a very limited number of chemicals where we may want to actually ever pick up a chronic effect, and so since that was such a small amount, we said for right now, no, we're not going to do that. Does that help answer your question?

MS. BROWN: If I understand you correct in that, you don't see the -- a chronic effect with --

MS. EDWARDS: It's -- it's the way that we're doing our risk assessments, how we do our margins of exposure and how we're using the no Ls, no exposure effect level, and how we're actually doing the risk assessments to come down to our risk management decisions. Lori.

MS. BERGER: I have a follow-up question to Amy Brown's question having to do with the pesticide safety education. In general, since we are seeing a reduction in resources going towards this area, but it's still an area of concern, of growing concern, how does -- what are EPA's thoughts on that. I really didn't hear a response on that, and then specifically with regard to GHS, what is your vision for an effective outreaching education system, especially in the international community where, at least as I perceive it, hazards are much greater.

MR. JONES: Well, on your first question, Lori, we're going to do an update in a few minutes here, gives you some sense as to what is going on in the PSEP funding that should answer that question.

MS. BERGER: Okay.

MS. LOWE: Internationally, actually, that's kind of an easier question because there is actually a focal point for capacity building for GHS implementation at the U.N. Institute for Training and Research, and they are developing pilot projects in countries for which they can get some donor funding and guidance materials for use by countries. Also, with the World Summit on Sustainable Development, there was something created called -- this is one of my pet peeves -- a type two partnership. There is no type one partnership.

(Laughter).

MS. LOWE: There are only type two partnerships, but hey, I didn't name it, but anyway -- and that's to bring together governments and stakeholder organizations to work on GHS implementation at the international level with particular emphasis on developing countries and countries with economies in transition.

The U.S. is an official member of that partnership. Our State Department was able to even find a lit bit of money to give them this year, and some of our stakeholder groups are also members of that partnership and have provided some resources to sponsor workshops and

the like. Both industry groups and at least one professional society that I'm aware of is a member of that partnership. So, there are efforts at the international level.

We have, you know, some of these running friendly spats about who has the harder job. Some people in developing countries say that we have the hardest job because we have to start from scratch and some of us in the industrialized countries saying, oh, that's easy. You just do what the GHS says. We have to redo everything. So, we've got the harder job, but the challenges are complex in both, and clearly with the developing countries, the biggest challenge, in my view, is actual implementation, not just having it on the books. Actually, there was a presentation on GHS at the intergovernmental forum on chemical safety last year that was very well-attended. It was a dinner event, and they passed out a CD with the GHS on it and very well-attended, and a week later -- I won't name the country -- a country called up the Unitar (phonetic) folks and said, okay, now we've done it, now what?

So -- so, there is interest, but it's going to be

hard.

UNIDENTIFIED MALE: Speaking of harmony, I think I'd like to sing the same song that Dr. Brown was singing from a State Department of Agriculture's perspective that it is really is critical when we're asking extension programs to take on expanded roles without funding to -- that's commensurate with -- to think pretty hard about that.

Also, I think the agency is probably aware of it, but I'd just point out that within the registration programs at the state level there will need to be some level of outreach there, as well, as we kind of backstop the agency with our -- our label reviews, and I'd like to just close with a question about the aquatic toxicity criteria. Could you explain the three different criteria?

MS. LOWE: Very briefly, I can, but I won't remember the cut-off levels. It's based on acute effects at -- and I'm not sure these are the right numbers, one milligram per certain volume 10 or 100, and I -- I can meet you during the break and show you the actual chart that has them, I just don't have them in my head, and so it would be sort of a L350 for certain kinds of aquatic

life.

UNIDENTIFIED FEMALE: And what would the -- the pictogram or the label statement --

MS. LOWE: Oh, we do have a slide for that.

MS. EDWARDS: Twenty-seven.

MS. LOWE: Twenty-seven, it's the dead fish and tree symbol --

(Laughter).

MS. LOWE: -- as it's affectionately known, and the -- the hazard statements, I can -- the GHS also has a chronic aquatic toxicity, which is based on combining acute with persistent criteria. Category one is very toxic to aquatic life.

Category -- and that's one milligram per liter, for fish, 96 hours, crustacea, 48 hours -- I guess everyone doesn't need to hear this. The second -- that would have warning -- all right -- back up -- category one, very toxic to aquatic life, the fish and tree symbol and the signal word "warning". Category two is the 10 milligram per liter, no signal word, no symbol, the hazard statement toxic to aquatic life, and category three is 100 milligrams per liter, no signal word, no symbol, harmful

to aquatic life, and that compares to what we use now for category one, which is this pesticide is toxic to fish unless we actually have fish kill data, in which case we say it's extremely toxic to fish.

UNIDENTIFIED MALE: Mary Francis, maybe I'm the only person that doesn't intuitively get what each of those means, but --

(Laughter).

UNIDENTIFIED MALE: -- what -- what do they mean?

(Laughter).

MS. LOWE: I'm sorry.

UNIDENTIFIED MALE: What do these little symbols mean? I mean, don't scribble --

UNIDENTIFIED FEMALE: Or can we guess?

(Laughter).

(Tape 3, Side A.)

MS. LOWE: -- back up and say that the U.S. was not really keen on getting a lot of these symbols, but we did it in the spirit of compromise that at least it draws attention to the label, but we all realize that it's going to take education for people to know what they mean. However, the ones on the top row are already in use. So,

we have explosive, flammable, oxidizers --

(Laughter).

MS. LOWE: -- I won't tell you what I call it. The skull and crossbones, that and the flame symbol are the ones that actually do seem to have some results in comprehensibility testing. Corrosion --

UNIDENTIFIED MALE: Corrosion?

UNIDENTIFIED FEMALE: That's a hand --

MS. LOWE: It's hand and metal corrosion, skin and metal corrosion --

UNIDENTIFIED MALE: Oh, my God.

UNIDENTIFIED MALE: I thought it was a ballistics thing.

UNIDENTIFIED FEMALE: -- bullets.

UNIDENTIFIED MALE: Yeah.

UNIDENTIFIED FEMALE: Bullets.

MS. LOWE: It's actually in use in the transport system, as well.

UNIDENTIFIED MALE: In foreign countries, do they use test tubes on their sides a lot?

(Laughter).

MS. LOWE: I don't know. This is the exclamation

point. This is quite literarily just an attention getter which --

(Laughter).

MS. LOWE: -- it means read the label. It deals with the lower classes of acute toxicity and with irritation. This is my least favorite. This is chronic health effects. There was no single symbol that -- that people could agree on that really would convey chronic health effects, and sometime when you have a lot of time I can show you some many more amusing versions and then the environmental --

MS. EDWARDS: This is your upside-down fish --

UNIDENTIFIED MALE: And what's the dead tree about?

MS. LOWE: It's sort of saving place for terrestrial toxicity --

UNIDENTIFIED MALE: Oh.

MS. LOWE: -- people still feel they could probably still use the same symbol without having a new one.

UNIDENTIFIED FEMALE: Will these be in the white paper?

MS. LOWE: They won't be in the white paper because I don't know how to do that on a word processor, but --

(Laughter).

MS. LOWE: -- they will -- they are on the web -- I mean, they are on the website, and I actually have a friend who has a better slide. Well, at this point, these -- as Ann was just mentioning, these are agreed to internationally after many, many, many hours of days, weeks, months, years of discussion.

In fact, the very last one, the agreed was the one with the white box around it because that was a question mark until the very last minute.

MR. JONES: We need to wrap this discussion up. I think perhaps we got your attention this time.

(Laughter).

MR. JONES: It didn't seem to happen last time, and one of the things we can talk about tomorrow is the degree to which you are -- want to have further engagement around this issue. As of PPDC, again, this white paper is going to be released in the not-too-distant future for public comment, and that's another opportunity people have

to participate in this.

With that, let's move on to the final session of this morning, which are some brief updates. I don't see Bill here -- oh, yes, he is. Bill Jordan is going to start us off, update on human testing, and Jim Roloffs (phonetic) on the mosquito label (inaudible) and Bill Diamond will be talking about outside education program budget sheets. All right, Bill.

MR. JORDAN: Hi, everybody. I'm going to tell you a little bit about what's happening on the front that Susie Hayson mentioned, the human testing issues. The major development since this group last got together was the issuance of the National Academy of Science's report on the human studies issues, how to approach them.

That report came out in February of this year, and I've talked to a lot of folks who have strong reactions to the report, but I think one of the things that it is pretty clear is that the academy gave EPA answers to all of the questions that we asked.

They didn't bob and weave. They didn't duck. They took pretty clear-cut positions on all of the questions that we posed to them in the scope of work, and

for that, we are grateful. It gives us something to work with, and that's what we've been doing since. I want to point out that you have four page news release that describes the academy's version of their report. It's a long document, and there's a lot more in it than simply what they packed into the news release, but I do want to mention a few highlights from it. The first is that the academy made a point to encourage us to think more broadly, not looking just at third party studies, that is studies done by people other than the Federal Government or folks receiving support from the Federal Government but to look also at ethical issues and scientific issues related to human testing when it's sponsored by the Federal Government.

They encouraged us to look beyond pesticides. In fact, the request to the academy asked them to consider the issue for the entire agency, not just for the pesticide program, and so the academy did, indeed, look into testing with other kinds of -- human testing with other kinds of potentially toxic environmental substances and said that those ethical issues that have been raised for pesticides also apply to the other categories of

substances for which testing might be done, and the third way in which it is suggested that we look more broadly is to look at a variety of different kinds of tests with human participants.

The controversies have arisen primarily with regard to the tests that are designed to establish no observed adverse effect level or no observed effect level in the human subjects, but there are other kinds of human studies that are performed intentionally dosing the participants, such as skin irritation studies, skin sensitization studies, studies that measure dermal absorption and other metabolism, or excretion, or exposure studies.

So, the academy said these studies, too, may raise scientific and ethical issues, and they gave us advice and encouraged us to think broadly about them, as well.

Even though they encouraged us to think broadly, they did suggest that there are distinctions among the types of tests, for example, or taking into account whether the entity performing the studies were subject to the common rule or not, and they also encouraged -- they -

- they encouraged to think about setting different kinds of standards or different approaches based on whether or not EPA has issued guidance and that the public understands what EPA's expectations are versus looking back into the past at studies that may already have been completed.

They have given us a lot of advice that we are currently working our way through. We are doing that in an EPA-wide human studies workgroup. It is jointly chaired by representatives from the two parts of EPA that have the most at stake in this issue, OPPTS, where the pesticide office is, and the office of research and development.

ORD not only performs studies with human participants and sponsors studies with human participants, but they also do a large share of the hazard assessments for other parts of EPA, hazardous estimates in which they have to confront the question of how to use or whether to use studies involving intentional dosing of human participants.

Our workgroup is making some headway. It's an area that some people are already intimately familiar with

and others are not. We're doing some bringing of folks up to speed on this. We're looking at a mix of different types of activities, and we have not made any decisions at all, but we could very well do things like issue guidance, policy statements. We are -- have said in an advance notice of proposed rule-making that we eventually expect that we will issue regulations to address some of these questions, and so that lies in the future.

The academy's report recommended that we consider reorganization of some of the functions involving -- involved with a review of human studies, and so that, too, is on the table, and we're looking at what that might involve, and then there are just things that we do that may not rise to the level of policy or guidance, but we have an ability to influence public opinion, we hope, and we might want to engage with people in the stakeholder community and have discussions about some of these issues, talk with organizations that are not regulated by EPA, such as professional societies and discuss with them what we would hope they could consider to be doing in terms of improving the attention given to ethical and scientific issues here.

I anticipate that you all will have interest in questions relating to schedule, and in that vein I think I can safely predict that we will not publishing any proposed rule this calendar year. There is a lot of work that will need to be done, even if we're attempting to put out some guidance, and so I'm not particularly optimistic about when we will be making any kind of proposed guidance available for discussion, but in the meantime, we are mindful of the instructions in the crop life decision which told us to review and make decisions on a case-by-case basis for deciding whether or not to use human studies mindful of high ethical standards, statutory provisions, and the common rule, and that's what we're doing as we are moving ahead, looking at particular regulatory actions or risk assessments that involve -- for which data are available that involved intentional dosing of human participants. We are looking at those studies on a case-by-case basis and making choices about how to move ahead.

That summarizes my remarks on human studies. So, let me stop briefly and see if there are any questions that folks would like to ask.

MR. LOCKWOOD: I'm wondering if you could give us some idea of when you expect to establish the Bioethics Advisory Committee -- the notice was published in the Federal Register almost a year ago, and I think it was somewhere around the first of the year that the designated federal officer associated with that anticipated posting a tentative list of participants in about two weeks, and since then, nothing has happened except the NAS report has been issued.

MR. JORDAN: Right. Thank you. The agency has a number of external scientific peer review groups. In the pesticide program, we use (inaudible) Scientific Advisory Panel. Other parts of the agency work with the Science Advisory Board, and what Dr. Lockwood is referring to is a notice in the Federal Register that proposed creating a subcommittee of the SAB that would look at bioethics issue.

For that subgroup, there were a number of different possible topics identified, one of which was looking at issues related to the consideration of studies that involve intentional dosing of human participants, and as we have talked internally, the Science Advisory Board

has consulted with our human studies workgroup to say, well, when do you think you're going to have guidance documents ready? When do you think you're going to have particular chemical decision that will be appropriate for consideration by the bioethics committee, and what we have said is, gee, we're not quite sure when that's going to come through, at least from the pesticide side, we are not going to point to any particular schedule, and they have been, I think, have been considering asking the other parts of EPA what they want to do about questions like the use of genomics and how much of a sense of urgency those other programs see there is -- there may be for convening this group, but as I suggested in the schedule discussion in my first remarks, it's not something that we are quite clear about, nor does it look like it's imminent.

So, that, I think, has led the SAB to move more slowly on that.

MR. LOCKWOOD: At least another two weeks then; huh?

MR. JORDAN: At least another two weeks.

UNIDENTIFIED MALE: Bill, I mean, obviously these are a difficult set of issues, but I'm wondering for

things like the human clinical patch test for irritation, for sensitization, things that the agency has traditionally accepted for purpose of registration, whether or not it is possible to think in terms of providing some clarity to registrants prior to the end of the process that I understand must consider other things and must work through some other issues, but is there -- is there a way to break out portions of this perhaps in an earlier time frame so that there would not only be clarity for registrants but also for your reviewers? I can't imagine that if you do case-by-case decision-making on each one of those kinds of submissions that that can be very efficient.

MR. JORDAN: Yeah. I expect that the case-by-case process will lead us to look at a situation, and when it's the first time we encounter a situation of that sort, we'll probably have to do a lot more thinking, a lot more working through the issues to reach a conclusion, but once we have done that, then the second time, or third time, or fourth time around, it will get easier, at least I sure hope so.

In terms of breaking these issues apart, there's

a sense within the agency that these issues are interrelated and that we need to have a -- a -- a position that's consistent not only across different parts of EPA but also across different types of studies.

We need to be able to explain to the public why we're treating things differently or why we're treating things the same way, and so I -- I am not optimistic that we'll have a police or guidance document that just deals with part of the -- the issues, but we still can look and deal with situations on a case-by-case basis.

UNIDENTIFIED MALE: Bill, I think that you -- I think you may have touched on -- I'm not quite clear -- are the counties expecting some kind of feedback of were these recommendations being followed, or are they going to have a way to keeping tab of what is being done, and they do not agree with what is being done, according to the recommendations? Is there going to be some way to get back to the EPA and tell them we are pleased with what you're doing? We don't think you're doing -- I mean, what's going to be the follow-up on it?

MR. JORDAN: I am very confident that there will be a lot of opportunity for the public to have input into

EPA's decision or proposed decisions on the policies, on the regulations, and as far as perhaps engaging with the National Academy, again, I think the -- the academy -- the group that was convened by the academy was convened for the purpose of writing a report. They issued the report and disbanded. I know that many of the individuals maintain an interest in it and will probably be among those who contact us, and consult with us about -- and let us know what they think of our path. Carolyn.

MS. BRICKEY: Well, having followed this issue for a long time and having read the ANAS report, I guess I disagree with you that it's very clear-cut. I think there's a number of areas where it's not very clear-cut, and I think we've remarkably gone through this adventure and come right back to where we started. I think it's just amazing.

So, the fact that you can't be specific with us today is not surprising, in light of that, but I'm just wondering when we can have more clarity about what you're going to do. To hear you say you're going to do case-by-case again, I think that's where we were before. So, you know, when will there be some guidance that we can look at

and say, yes, they're doing this, or no, they're not doing that?

MR. JORDAN: Well, I would love to have clear guidance sooner rather than later, and I'm sure that, you know, for many people within the agency that would be also a good outcome, but I've got to tell you, the level of discussion and the controversy within the agency is -- just makes me pessimistic that we're going to cross that finish line anytime soon.

MS. BRICKEY: Was there serious consideration of leaving a moratorium in place in light of all this?

MR. JORDAN: We were sued in the U.S. Court of Appeals for D.C., and the U.S. Court of Appeals said you cannot leave the moratorium in place, and so, no, we cannot do that.

MS. BRICKEY: Okay.

UNIDENTIFIED FEMALE: This is further to Pat's comment about I think there may be certain categories or types of studies that clear -- there is clearly a difference, and this would be, in particular, products that -- testing for products that are made for direct human application, such as insect repellants.

When the moratorium was in place, we actually -- this became an issue as to whether efficacy testing could be done on humans, and I think there is clearly types of studies or categories of studies, you know, skin irritation testing on products that are meant for skin application that there -- that it should be clear that those kinds of testing are appropriate.

UNIDENTIFIED MALE: Not to be contrary, Carolyn, but I -- I thought maybe we could go all morning without you and I disagreeing, but I think the NAS report is incredibly clear, given the complexity of the issue and the history on this particular subject, and I would commend Bill for a really nice summary here this morning.

MR. JONES: Well, the good news is that you did go all morning. The bad news is it's afternoon now, which means (inaudible) --

(Laughter).

MR. JONES: Thanks, Bill. We will break for lunch at 12:30. Jim, why don't -- and we may -- which may mean we leave the PSEP discussion for when we get back this afternoon. Jim, why don't you --

MR. ROLOFFS: Okay. I -- I won't need very long.

This is a quick update on our project to develop recommendations to improve the labeling of adult mosquito control products, and as many of you will recall a year ago, we came to this committee with a set of initial recommendations to do that, and those recommendations have been developed by an ad hoc group made up of EPA headquarters, EPA regional offices, and some state agencies.

We had a panel discussion. A lively discussion followed, and the message we took away from this committee was that we should go ahead and turn those into formal EPA positions instead of these ad hoc initial set, and so we proceeded to develop what we call a pesticide registration notice, and it has now been published, and it was published on April the 28th, and it is part of your package, I believe. The comment period is 90 days. So, that closes on July the 27th.

As of yesterday afternoon, our docket contained two comments, and none of them from anybody at this committee. So, I invite you to comment, by all means. This is -- represents a broad group of stakeholders.

You took an interest in it, and now you have

specific language to focus on, and I look forward to see them. Thank you.

MR. JONES: Jim, I have a question. The -- we've had a number of discussions around -- as you mentioned, around this issue. Do -- will the transcripts from those meetings be considered as comments?

MR. ROLOFFS: I wouldn't do that, and I'll tell you why, in April of last year what we presented, the initial comments have changed --

MR. JONES: Um-hum.

MR. ROLOFFS: -- they've evolved. The briefing that I gave this committee in October of last year, I studiously avoided putting specific language in front of them because I just wanted to discuss the principles, and we hadn't finalized the language.

MR. JONES: So, for many of you who have given us feedback at this meeting, it really is important if you want to have your comments considered in our -- in -- in the process --

MR. ROLOFFS: Right.

MR. JONES: -- of the notice that you submit those, not think that the -- a comment you may have made

at this meeting has been included in the agencies. I just wanted to clarify that because I know we heard from a number of you, some in support, some partially in support, and some with particular problems with certain aspects of it. So --

MR. ROLOFFS: Right. Thank you.

MR. JONES: Julie.

MS. SPAGNOLI: Just this is a quick question on, you know, the implementation, and I think this is -- you know, we run into this often with these kind of labeling requirements and labeling requirements done via PR notice, but what's the -- you know, kind of what's the general plan for trying to determine products that are in the scope of this PR notice, and then, you know, seeing that those products are updated accordingly?

MR. ROLOFFS: Well, as you know, PR notices are directed to registrants, and this one specifically says this is for things that are labeled for ultra low volume application for adult mosquito control, specifically excludes larvicides, excludes homeowner products, et cetera. So, I think the universe is fairly small.

MS. SPAGNOLI: It's pretty -- it's pretty clearly

defined --

MR. ROLOFFS: Right.

MS. SPAGNOLI: -- as to what products are impacted. So, but I mean, is it -- so, is -- is the agency taking any action to -- for them to determine which products are impacted?

MR. ROLOFFS: I haven't so far, but it wouldn't be that difficult to do. I think the total universe of things that might meet that, there's less than 200, and the ones that really meet it, it's probably a small fraction of that if you just go after adult mosquitos.

MR. JONES: Okay. Well, what -- we'll need more than two minutes to do the PSEP funding discussion. So, I don't want to shortchange that, and I don't want anyone to get cranky because they're hungry. So, why don't we break for lunch. We'll take an hour, and we'll be back at 1:30. Thanks.

(Whereupon, a brief recess was taken.)

(Tape 4, Side A.)

MR. JONES: -- first session in the afternoon, pesticide safety education program. All right. Bill --

Bill -- and this is the Bill Diamond that I referred to earlier, who is the new, as in the last five or six months, director of the field in external affairs division. Bill's going to give us an update on PSEP.

MR. DIAMOND: Thanks, Jim. I'm just going to give you a brief summary, and then we can have any questions or -- or comments in terms of what we're doing with that.

For those of you who aren't familiar, PSEP stands for the pesticide safety education program. It's one of our cornerstone training activities for pesticide applicators. It's conducted through the state extension services. In funded in part by grants from EPA processed through USDA. However, most of the extension service providers also have alternative sources of funding, as well, to leverage the resources that EPA puts into the program.

Last year, EPA, for a variety of reasons, was only able to provide about $700,000 to this activity. That was a significant decrease from the historical levels that have gone into this program for a number of years.

USDA was able to come up with some funds to

supplement that EPA funding in the amount of $425,000. That gave us the total federal contribution of approximately 1.1 million dollars which, again, was a significant reduction from the historical levels.

In FY 2004, we received our budget allocation in late winter. That was about six months into the fiscal year. The extramural budget included, again, reductions and some constraints. Nonetheless, because of the priority we think we attribute to this program and the value returned, when we did our budget allocation, we decided to add $500,000 of extramural funding to the base $700,000 that we were able to come up with last year for a total of 1.2 million dollars.

While that didn't get us back to the historical levels of funding for this program, it still constituted the largest single item in our division extramural funding accounts. We've just finished our internal processing of that grant money at EPA, and we've only recently sent it over to USDA to process their mechanisms to get it out to the state extension services.

In terms of looking to the future, we're working

with USDA to launch a program review, and that's -- we're going to try to conduct that over the next couple of months. The idea is, you know, just basic good management that we ought to be on a periodic basis trying to determine if we are achieving the program goals as efficiently and as cost effectively as possible. With the budget issues, we think that it adds another compelling reason to take a look at the program. It also is a -- a process that will allow us to deal effectively with the increased emphasis on demonstrating outcomes in terms of performance accountability measures that is getting greater attention under the Government Performance and Results Act and the Office of Management Budgets instituted program reviews, their program assessment review tools that they're doing for every aspect of the Federal Government that receives funds. We're basically going to try and do a comprehensive but quick review of the program, going to try and basically answer the question of whether or not we're doing the best job possible in the best way possible with the resources available.

We hope to gather some data on -- not only on

priority needs, and audiences, and actions but also materials and services. Are there any gaps? Are there any things that we can do, lessons learned across the board from different people and maybe brainstorm some alternatives and also consider basic operational efficiencies in processing the money.

We intend to try and get some data and input from critical stakeholders and hope to complete it by this fall so that we can possibly initiate any program improvements by the next fiscal year when we get next year's funding and grants.

I think that what we're going to have to look at is not a bottoms-up review but find -- see if there are some suggestions given the current funding situation and continued prospects for trying to look the best possible ways to accomplish this important activity for both us and for the recipients of the training. Questions?

UNIDENTIFIED FEMALE: Yes, Bill. You mentioned the need for -- the need for accountability and performance outcomes. There is a system within USDA that has current been used for the last couple of years that has very detailed indicated and APSE and the pesticide

safety education coordinators have asked in the past if there are any indicators that are specifically not being met, if there are problems, if there are others that we need to include, and we haven't received any real feedback on that. Is there something that we can tell our pesticide safety educators that we actually need to address that you're not getting from those reports?

MR. DIAMOND: I think that we've got to look at, and this is something that's not unique to this program, is to look at the current measures we've got and then look at the standards that we're being held to now.

Historically, in many programs what you've got is more output measures than outcome measures. The direct measure in terms of being is that dollar that the Federal Government is investing, contributing directly to the strategic goal of public health or environmental protection. If they are, then that's fine. We just have to make sure that they've got the proper data quality, issues of burden of collecting that data. If not, then we've got to look -- there are some steps that we can go to kind of upgrade from outputs to outcomes, and that's the type of thing we've got. I'm not intimately familiar

with the ones that the USDA has for this program, but clearly we're going to be working closely with them to try and make sure -- either verifying the ones we've got or try and improve them.

UNIDENTIFIED FEMALE: That is a good point. I firmly support the idea of outcomes rather than just the number of people trained, the number of booklets given out, and all of the states have turned over to that in the last couple of years, the outcomes are now in terms of things like behavioral practices changed.

MR. DIAMOND: Right. In our initial discussions, those are the types of things that we think are the areas that we should be looking at, and the exercise is not only to try and make sure that the extension services, as the front line providers are doing that, but if we do have those new measures, then we can incorporate them into our accountability systems, as well, so that we're all talking about the same set of notes.

UNIDENTIFIED FEMALE: And when do you foresee -- what do you foresee the timeline of this review group being?

MR. DIAMOND: We're -- we're working with USDA

over the next couple of weeks. We've already talked to (inaudible) in terms of some of the conversations we have with him and your group. We've talked to APCO. We're trying to put together an outline in terms of framing the question so that it's fairly focused along the lines of what I was saying. We're hoping to launch that over the next month or and try and complete it by October 1 is the target date.

UNIDENTIFIED FEMALE: I just want to argue once again for getting something done very quickly because, again, as the state programs fold and lose people and personnel who have historically been responsible for these training programs, even if the review process determines there is a better way to do things, and certainly we can all improve the programs.

If you -- once you lose the people, you don't get them back, and once you lose the ties with the groups that we train, both applicators and -- certified applicators and non-certified applicators, it's very hard to pick up those ties again.

UNIDENTIFIED MALE: Bill, we, at Crop Life -- and our members share the concerns that Dr. Brown has

expressed and in fact stated it in the letter to Jim that we sent over yesterday. One of the ideas that we expressed in our letter was the suggestion that perhaps the fundamental problem now from 2003 and 2004 with this problem recurring might be attached to the fact that it's a grant program as opposed to being a budget line item, and I wonder if you could address whether, in fact, that is part of sort of the organizational, structure problem inherent here, and if -- if the education money were moved into a budget line item, would that help with year to year consistency, and is that a regulatory step that this advisory committee could advise the program to take, and would that be helpful, or is that a legislative matter for which those of us who are registered lobbyists can go to the Congress and pursue? Thanks.

UNIDENTIFIED MALE: I'll take that -- the -- I learned this one from Steve Johnson, a good lesson, that is we support the President's budget, and --

(Laughter).

UNIDENTIFIED MALE: -- he -- the PSEP funding has been discretionary to EPA and to OPP. We have chosen over the last 20 years, without any directive in the

appropriations, to allocate a sizeable part of our discretionary dollars to that.

So, it has not been a wide items. It's been part of our appropriation that we -- that's been discretionary that we've chosen to put the amount of funding that we have over the past 20 years, and as you've heard, it's been -- it was reduced two years again and then again -- or last year and then again this year.

UNIDENTIFIED MALE: So, I'm not sure I understood the answer to my question, is it something we should do here or that we should all go to the (inaudible) --

UNIDENTIFIED MALE: It's certainly not something that the executive branch would advise you on, as we support the President's budget.

(Laughter).

UNIDENTIFIED MALE: So, if we were to have a motion from the floor here as an advisory committee recommending to EPA that this be moved into a more stabilized budget item that would be within our purview as a committee?

MR. JONES: I believe so. That would be advice you could -- this committee could choose to give, if it so

pleased.

UNIDENTIFIED MALE: Good. I'd like to make that motion.

MS. SETTING: Second.

MR. JONES: I do think it's -- it's fair for the rest of the members of the PPDC to realize that that -- that the choice around funding are about trade-offs between this program, things like worker protection, PSP funding, and other discretionary dollars within our -- within our pool.

I actually asked the group at our last meeting if we had budget choices to make, would the -- would the PPDC like to get together in an ad hoc way on the phone perhaps in a conference call and give advice to the agency, and you all said, whoa, no, that's not really what we're here to do.

So, I think that -- that it's important to recognize before you take on the advice in this area that you recognize that we are dealing with a zero sum gain and that's you're talking about trading off this versus other, and of course, it is advice and the agency will take that under advisement if you choose to give us that advice, but

we have a motion and a second.

Jay, would you sort of repeat what your motion is?

UNIDENTIFIED MALE: That in order that the pesticide education program be on a more stable year-to-year financial footing that it be moved from a grant to a budget line item status within the program.

MR. JONES: And I think, Mary Ellen, you seconded that; is that --

MS. SETTING: Yes.

MR. JONES: Okay. Is there anyone -- do it the same way we did the last -- are there any members of the PPDC who would like to make sure the agency knows that they're not -- they don't necessarily want to support such a recommendation. I'm not -- I don't want to get us into a voting, but I would like to hear if there are others who are not.

UNIDENTIFIED FEMALE: Just clarification just so I understand, this would make it not -- no longer the discretionary spending? It would be a budget item, is that what --

UNIDENTIFIED MALE: Right.

UNIDENTIFIED FEMALE: -- you're saying --

UNIDENTIFIED MALE: But -- but they obviously, the --

UNIDENTIFIED FEMALE: -- just so I'm understanding --

UNIDENTIFIED MALE: -- administration determines what their budget is -- approach, and the Congress concurs, but --

UNIDENTIFIED FEMALE: Um-hum.

UNIDENTIFIED MALE: -- it would become a little more defined and explicit, I think, under this approach rather than leaving it as something that is decided in the way of a grant, amount out of a pool of money after the budget year has started.

UNIDENTIFIED FEMALE: So, it's designated for that purpose and not necessarily --

UNIDENTIFIED MALE: By me.

UNIDENTIFIED FEMALE: -- taken away --

UNIDENTIFIED MALE: Right.

UNIDENTIFIED FEMALE: -- but not necessarily taken away from --

UNIDENTIFIED MALE: Congress is not mine

(laughing).

UNIDENTIFIED FEMALE: -- not necessarily taken away from some other thing because it's already been designated --

UNIDENTIFIED MALE: Well, no, it would be -- it would come out of something else.

UNIDENTIFIED FEMALE: Something else, okay.

UNIDENTIFIED MALE: I can't imagine we're going to get an increase overall.

UNIDENTIFIED MALE: The total bucket of money shrinks, it's going to have to come from somewhere else --

UNIDENTIFIED MALE: Yeah.

UNIDENTIFIED MALE: -- right.

UNIDENTIFIED FEMALE: So, I guess the question is is then what does it come out of?

UNIDENTIFIED MALE: Well, I gave you some examples. There would be PSEP funding, worker's protection funding, potential groundwater dollars that go to states, potentially endangered species, those are the general discretionary --

UNIDENTIFIED FEMALE: General communications.

UNIDENTIFIED MALE: -- general communications

materials, yeah. Amy.

MS. BROWN: And yet, each of those programs that you mentioned has an educational component which currently the pesticide safety education programs address with no funding.

MR. JONES: Um-hum. Rebeckah?

MS. FREEMAN: I would just like to build on the point that Amy and Jay have made that more is being asked of less, and we've seen some accounting confusion in the past that caused almost a zeroing out and finding money woefully inadequate last year, a reduction in funding that I suspect you guys didn't ask for but that was done for budgetary reasons at the administrations level, as were all discretionary funds at all agencies, but we're dealing with a situation that we saw steady funding in a program weren't -- you know, weren't even as ambitious to, I think, even ask for more funding. We just wanted it to stay at the 1.88 or wherever it was, 1.8 that it was and just -- just stay there. We understand it's a tough budget year, and I think that's what we're saying, it's just the predictability of the states to have to know and

-- and the programs to have to know what they have to work with in order to schedule -- preschedule how they're either going to educate their certified work -- their certificate applicators or the other workers, and the more we ask out of people and the more label changes we make, and everything we've talked about all day long has related to what more we need to communicate, how better -- if we can make all the rules we want inside the beltway, if they're not being applied out there, the workers aren't being protected. The fields aren't being protected, and the environment is not being protected, and all of the challenges that we are talking about here today, you know, the big component, the biggest, most effective component of what happens doesn't happen inside the walls of my office, or your office, or anywhere else, it happens out there, depending on how people used what we register and what we work on, and you know, that is something that we're forgetting here, even if we're taking away from someplace else where the rubber hits the road and the rubber is not hitting the road right now in the fashion that it should, and it's very much a concern for my members.

MR. JONES: Why don't I suggest because this -- this choice will not have to be made again until after our next meeting -- we will have an '05 budget choice that we'll have to make next -- next year, and I'll still let you sort of give us advice on your resolution that we, in our next meeting, which will be in the October/November time frame, come back -- we've -- we've done this before, but we can do it again, and it will be in the context of this choice, what is the discretion that we've got around our budget, what has it historically been, and what -- so you have the full information about what the trade-offs are, again, you know, which we will do that. I think that's just -- it's important for those of you who may represent a different perspective to know fully what you're being asked to -- to advise us on, and I think you have to have those numbers to do that fully informed, but we still -- I'd be happy to sort of take the advice of the PPDC as it relates to the specific issue you've -- you've offered Jay because that actually does occur in the budget process that would occur before then.

So, we have a motion on the table. We have it seconded. I would like to get a sense if there is some

dissension amongst the membership now or if I have a unanimous -- Carolyn.

(Laughter).

MR. JONES: Steve.

MR. BALLING: Well, you said it so eloquently, Jim. I'm not against motherhood and apple pie, and I, you know, obviously the PSP program is -- is critical to making sure we continue to use pesticide safely. However, before I say that I want to move it up to the top of the priority list, I want to see what else is being moved down, and I think you've already mentioned some that are fairly important programs, and I'm not -- I wouldn't say fund PSP entirely until I have some sense of what else the trade-offs are. So, that's my (inaudible) --

MR. JONES: Carolyn.

MS. BRICKEY: And I echo what Steve said.

MR. BALLING: Oh.

(Laughter).

MR. JONES: Does anyone else want to --

MR. BALLING: We should have lunch.

MR. JONES: -- proffer some advice to the agency? Okay. I get then the sense that it is a -- is a near

consensus opinion that we should pursue, in our budgeting process, a line item approach to PSEP funding, and the agency will take that under advisement with some dissent noted. Thank you.

UNIDENTIFIED MALE: But we'll talk more about it at the next meeting.

MR. JONES: And at the next -- at the next meeting, we'll come back with --

UNIDENTIFIED MALE: Yeah.

MR. JONES: -- here -- here's how the choices -- these are the context within which these choices are -- are made --

UNIDENTIFIED MALE: Right.

MR. JONES: -- the other discretionary pools of -- of money. All right. Very good. Thank you.

MR. JONES: Well, our next topic, I expect, will have similar degree of PPDC participation on. We have been working so hard on endangered species over the last couple of years that it's been very hard to stop, take our breath, and engage in the kind of public dialogue and discussion that we have become accustomed to and I know that you all have become accustomed to in our program, and

so today what we are going to do is we start to put our -- step our foot into that -- our toe into that water is, first, give you an update on all the different kinds of things that we have going on as it relates to endangered species and the (inaudible) pesticide program, and then we're going to put forward a proposed approach for your consideration and advice about how we can, as a program, fully get our arms around endangered species act requirements and get fully into compliance over time, and so Bill Diamond is going to sort of us walk us through both parts of that.

MR. DIAMOND: Thanks, Jim. We discussed this topic at the last PPDC meeting. At that time, it was mostly educational, a little discussion. This time we're going to try to flip it a little bit, so with a little education in the form of updates and then hopefully to get into a more deliberate discussion in terms of the (inaudible) move forward with this overall.

I'm going to start off with a little summary of some of the activities that have taken place in the last six months or so because it provides some background and context to where we are.

We are going to pose some questions of what's going on, talk a little bit about our draft program approach, and then we're going to hear from Berlison Smith, USDA, in terms of perspectives to the actions to the proposed -- to the proposal and also Clint Reilly (phonetic) from the Fish and Wildlife Service will also give us some reaction before we open to questions, comments, suggestions, and reactions.

In terms of the quick updates, everyone is familiar, I think, with the (inaudible) regulations that were proposed in January of 2004. These would govern the future interactions of how EPA consults with the services when we make a determination that may affect under our endangered species review.

Right now that's -- that was proposed this past January. The comment period closed at the end of last month. There were several hundred thousand comments received on -- under that. The services are now organizing those comments for review in terms of grouping them together, what issues are identified. That's no small task when you've got that large a number of comments, even if a number of them are fairly specific in

terms of just expressing opinion overall.

The (inaudible) for those final regulations that we originally sent out (inaudible) and obviously that is continuing somewhat in terms of the nature of the comments, the issues that are together, but it is something that we feel fairly strongly about that we've got to move ahead, given all the work that's been invested into that.

In terms of a parallel activity in terms of that first counterpart regulation set the structure for EPAs service interaction on this issue. We've also got the field implementation component. Once we do make a determination in this program, how we're going to go about implementing it, how we're going to communicate that (inaudible).

There was a proposal that went out in December of 2002 that laid out the framework of what our approach would look like. We are drafting a final approach based upon the comments received, and again, we anticipate final publication this fall in terms of laying out the groundwork and the framework for how that's going to take place.

While this was going on, in terms of the visible framework for the program here, we're doing a lot of internal getting ready to find -- make sure that we're moving up to where we should be in this program overall. Part of that is just deciding what it is we actually have to do.

One of the reasons we're in this hall is because we haven't done anything that we either probably should have or wanted to, given resources and other constraints, but the first part that we're undertaking is kind of a workflow analysis within our division but also with our sister divisions that were involved in this process to try and identify explicitly what are the steps that have to be done, what issues, what questions, how we're going to do that so we've got as efficient a process as possible. I think you'll see that when we describe it in a little bit more detail later on.

In terms of it takes money to do these things, as we've already been talking about in terms of anything, we're staffing up to try to do a better job on this. We've had a bare bones, skeletal staff in this program for a number of years.

We are having significant increases, probably not enough, as with any program, to do anything but significant enough that we are going to be able to upgrade the quality and timeliness of our reviews to figure back into the process here. That's good news.

The bad news is it takes a little time to hire those people. It takes a little time to get them up to speed. We want a dry path in a couple of years from now. We want the program fully implemented (inaudible), but right now what we have been including are some people -- we think we've got some good candidates that are starting to come on board, and we can start that (inaudible) to be able to do our job, not only in terms of specific review in our organization but the other generic reviews that are going on in other parts of OPP.

As part of that, we're going to have to identify not only in terms of how we get the work done but how to (inaudible) it for internal measures and to make sure that we stay on track and accountability to perform its measures in this (inaudible) as other ones, as well. We look at efficiency measures. We look (inaudible) measures, hopefully, or there are some that are good

indicators in terms of progress for our activities but also in terms of the quality of our reviews when we ultimately get (inaudible).

Taking advantage of new tools and trying to identify (inaudible) enhancement to move the process quicker and get us on board but also to allow us to communicate more effectively (inaudible) or the options before us on making some of these decisions is something that we're investing in. Again, it's going to take some time, but we think there's a lot of opportunities there for efficiency improvements as well as clarity and (inaudible) in our operations.

We've used some of these numbers here to get a sense of just the workload and the challenge that's before us (inaudible), and I'll apologize for the -- some of these numbers up here in terms of -- my rookie status. You've heard of up to 1200 active ingredients this morning. We've got 1900 pesticide products, that's supposed to be 19,000, but you've got approximately 20,000 pesticide products that potentially could trip some of these endangered species (inaudible).

Each product has potentially one to 100 different

uses. If you've got that combined with the 1200 we listed threatening endangered species, you start to get a fairly large universe, and those species exist in approximately two-thirds of the counties throughout the United States, which gives you a sense of the scope of what's involved in terms of the starting point, the baseline that potentially you'd have to work with.

If you take a sense in terms of what that means for actual workload when we get down to the actual workload process and analysis for that, we're talking about -- if you can assume that a typical active ingredient has maybe five products with four different use sites and it trips the level of concern for maybe just two groups in terms of the species that it may have a problem for. So, you're narrowing the universe down in terms of specificity here, but it does get exponential (inaudible).

If you got three mammals in the area of potential use and maybe 10 fish in the area of potential use there, then you start to have to do some multiplication to see those specific determinations that you're going to be engaged in here. (Inaudible) you have the five products times the four uses, you get 20 scenarios, 20 scenarios

times the impacted species, you get up to 60 different determinations. If you have 20 scenarios of fish and -- mammals, you have 200 determines gives you a sense potentially of what -- the specific determinations we're going to have to make in terms of whether it has no affect, may affect, or (inaudible). Just for this one type of active ingredient which could have 260 geographically discrete determinations for this particular (inaudible) that's important because you've got variable factors there that have to go into those determinations obviously depending on the locale.

In terms of what we were trying to accomplish when we designed the program, some of this is motherhood and apple pie, bears repeating, obviously full compliance with endangered species act requirements for the agency, that's a given, but it hasn't been full in practice to date, that's why we've got such a high step up here.

The efficient use of resources: I talked about the increase in resources that we've got that are significant, but they're not open-ended. We're going to have to manage it sufficiently, take a long-term view as opposed to a short-term focus, and then obviously when

we're doing these things they're effective, quality decisions. There's no sense in terms of doing something quickly if it's just going to be thrown back to us here.

So, those are basic principles (inaudible) committed to. Some of the challenges here, this is not a one time effort, obviously. We've got to have a sustained approach to full (inaudible) compliance. This is something that when we get our practices in place, we're going to have to go through this repetitively for a number of different products and A.I.s.

I talked about effective compliance but also try to do it expeditiously, design processes that allow full consideration of data, full input by all interested parties, and full and open disclosure and public participation, which is one of the difficult challenges we want to talk to you about.

The tension there is one that's going to be driven not only in terms of our own needs in terms of what our priorities are but also in terms of the outside interests. Some of the priorities that we have on the table today are driven by litigation rather than by good, informed (inaudible) decisions in terms of deciding up-

front (inaudible). We hope to get out of that so that we can focus on the rights things at the right time with the right quality, and then, as I mentioned, public participation is something that's very (inaudible) to insuring that we get the job done right, get all the information on the table when we're making our determinations and then fully explain and document those decisions so people can agree or disagree, challenge, understand, but hopefully we can communicate, and implement them, and deal with them in an appropriate manner.

In terms of how we're going to do this type of process effectively and efficiently, we're going to try and do this obviously in terms of not recreating the wheel to the extent it's possible, going to try and use existing practices to the extent we can. We've talked about registration with you this morning. That's a building block to what we're doing.

We're going to talk a little bit now in terms of just a quick flash for the core programs and what's engaged with them right now kind of as a background in terms of when we say we're going to overlay on top of

those things that we've got the context here. This case, I'm going to ask my colleagues first -- Debbie Edwards to talk about where we are on the new registration, and then we'll have (inaudible) talk about the registration review and then a quick snapshot on regis -- registration review. Debbie.

MS. EDWARDS: Okay. Thank you. Well, just to give you a sense of where we are with re-registration, and you can see from this slide, we had 612 cases overall to look at for the (inaudible) that were registered before '84, and we're about three-quarters of the way there right now.

We have 155 decisions remaining, and you can find the schedule for completion of those decisions out on the table, if you didn't already pick it up. It was recently published on the -- on the web. What that schedule shows is the completion of all of the (inaudible) decisions by August of 2006 and all the remaining (inaudible) decisions by October of 2008. Does everybody hear me?

(Laughter).

MS. EDWARDS: Did I talk loud enough? (Laughing) sorry about that. So, what we're doing is using a robust

public process, which I'll actually talk about more tomorrow in an update we're going to have, but we're -- we're planning to use the existing public process to the extent possible to publically vent many of these endangered species issues and solicit public comment, and we've actually been receiving a number of useful comments currently and some of them from the Fish and Wildlife Services. So, Lois.

MS. ROSSI: Thanks. With regard to the registration problem, as you all know, we're -- our registration program now is under the pesticide regulatory improvement act where EPA -- it's a fee for service program or fee for service system that would establish time frames for the various decisions.

Typically, the program which includes decisions made in the antimicrobial division as well as the biological and pollution prevention division has made between 25 to 30 new active ingredient decisions a year, and with regard to new uses, it's been around two to 300. So, we'll see how fee for service affects those -- those numbers, and of course, most of you know that it's authorized until the year 2010. So --

UNIDENTIFIED FEMALE: In terms of registration review, I think you all have heard a fair amount about that's going to proceed earlier today. Obviously, we'll be looking at the chemicals on a 15 year cycle. I don't think I need to repeat most of this. We hope to have final program in place by August of 2006, which will be kind of dove-tailing out of the existing re-registration program, and one of the things we hope to see through the pilots is how we can pull out some of the complex endangered species issues and kind of look at what the costs will be there.

UNIDENTIFIED MALE: I think we'll now have (inaudible) Williams, who is the chief of the environmental field branch, the front-line manager for us go through in terms of how we're hoping to design the program to overlay on top of these (inaudible).

MS. WILLIAMS: Thank you. Thank you all for having us here today, and listening to all of this, and helping us with this. It's a very difficult situation. Currently we are focusing our resources that conduct species-specific endangered species assessments outside of the registration and re-registration processes, and the

main reason for that is that we're trying to keep up with the litigation schedules that we're under and that we have to comply with.

Those are, in general, focused on either specific species that people had concerns about or specific pesticides in one case but mostly on specific species, which gets you part-way to the -- to the end of the game but only part-way to the end of the game.

On the next slide, what we're looking at doing is rather than having kind of a separate process that -- that runs at its own pace to look at parts of pesticide registrations, what we're proposing to do is to incorporate the species-specific assessment process into the overall process that were just summarized, registration, re-registration, as long as it lasts, and the registration review processes.

On this graphic, the red arrows indicate kind of interactions that don't go directly to those registration, re-registration, and registration review processes. On the -- is there a pointer here? Can I borrow that? Thanks.

If you look here, this just indicates a chemical

coming in the door for whatever reason and action is initiated to review it. At that point, a screening level assessment has begun, and that's the assessment that most of you are probably familiar with more as the environmental (inaudible) and effects division, ecological risk assessment -- the red arrow indicates that at that very early stage, we would -- we would be coordinating the species-specific refinements of this with the people actually doing the screening level assessment.

If we got to a point where we were confident there would be an issue of the species and we had a package prepared, we could, at that point, initiate consultation with the services as necessary at a fairly early stage in this process.

Continuing on, after this coordination is done and we've come to joint conclusions, joint meaning the screening level assessment is done and we have indicated what the species-specific refinements look like, that information then would -- would go back down into the registration and re-registration processes to look at assessment integration, and what I mean is this is the place in Lois's and Debbie's division where they take the

eco-risk assessment and the health risk assessment and -- and they integrate all of that to get a picture of what the registration status of this pesticide should be.

We would continue being involved, although not as directly, throughout that assessment integration process and then into the phase where mitigation, if required, is -- is identified to mitigate any risks from the pesticide. Once the mitigation requirements are discussed among the appropriate parties and decided on, eventually that -- that mitigation would be reflected in labeling of the product, but for endangered there's -- it's kind of a whole other leg of implementation that would branch off from that in addition to the label of the product, and that would be the development of information articulating the specific requirements to protect listed species from that pesticide and then ultimately field implementation of those documents or that information so that the users out in the field will know what they're expected to do and they can provide the appropriate protection. Next slide.

If we are successful in doing this, this is kind of rehash from a -- a different angle and -- and some of the things you just heard, these are time-lines and they

are (inaudible) increments, 2004, six, eight, 10, 12 all the way to 20, 21, which puts us at the 15 year date for the registration review program if it starts when it starts in 2006.

The top line in this is the registration process, and as you can see, there is an arrow here because we anticipate that does not have an end. It continues on and on. The second -- the second bar on this chart is registration review, which is the 15 -- 15 year cycle review of each pesticide, and then this third bar, as Debbie mentioned, is the remainder of the re-registration program, which we anticipate will be done in 2008. If you take these programs and kind of stack them on top of each other like this time-wise, if you look up here, in the time frame from 2004 to 2006, we'll be looking at an estimate 50-plus new active ingredients coming through (inaudible), and I don't know the exact numbers that Debbie has articulated, but half of what we need to get done would be 75 registrat -- re-registration eligibility decisions.

In the following two-year period from 2006 to 2008, you have that same universe, but then you're adding

in the first two years of registration review and with an estimated 80 decisions per year in this two year period, you're looking at adding in 160 registration review decisions. In each subsequent two year period, the re-registration program will be completed. So, that falls out, and you would be looking at 50-plus new actives and 160 registration review decisions in each two year period for the 15 year cycle.

What we're proposing in the process that was on the previous slide is to try and tap into this -- this process and these time frames as much as we possibly can with the goal of completing work on endangered species before a chemical comes out the door finally from any of these three processes, and again, this shows the -- the time frame for re-registration. At the same time -- I'm sorry -- registration review.

At the same time, we recognize there may be some outliers that will need attention outside this process, so this bar down here is just a -- a -- as you see, much smaller, continuing ability to handle some situations outside these processes should those needs arise.

We would anticipate that over time, the size of

this particular process, which is the one currently used to address the litigation, would -- would shrink as we get more adept and more skilled at actually incorporating the endangered species specific assessments into our kind of core processes. Okay. Next slide, next slide. Thank you.

So, the long-term approach that we're looking at implementing is to do assessments and limitations based on a review first of an entire pesticide, rather than looking at one species here and one species there.

One of the major values of this is efficiency in the process. We're not going back and actually reviewing a chemical 12 different times because there are 12 different species that we need to look at. We plan to look at the entire chemical all at once, get the assessments done for all species that could be impacted by that chemical, make the decisions, and implement those decisions, and again, the long-term goal here in this proposal is to include the now kind of remote endangered species assessments into our standard registration, re-registration, and ultimately registration review processes. Next slide.

We believe that this will achieve a number of the objectives and address a number of the challenges that Bill articulated at the beginning of his -- his opening remarks. First, we believe that this will assure that decisions regarding the registration status of a pesticide, whether that determination comes out of registration, re-registration, or registration review. We'll include all of the relevant considerations, including considerations for potential effects on listed species and their critical habitat, and that then would be our first step in actually addressing those potential effects. We can't address them, obviously, until we identify them. So, we would hope to use those processes in kind of a time step order.

Secondly, it will help ensure that when a decision is made through any of those processes, there is some certainty for two of the Federal Government's constituents, A, the species, and B, the pesticide users.

Right now I think there's a lot of uncertainty on both of their parts in terms of, A, the protection they're getting, and B, how they can plan their schedule for pesticide applications that may be necessary in the coming

season.

If we are going about this in a logical stepwise fashion, when the decision comes out the door, the species will have protections that we can put in place pretty effectively, and the growers will be able to plan for the next growing season what pesticides are available to them and what pesticides may not be available to them because of limitations that were necessary to protect the species.

Third, we believe that incorporation of the endangered species specific assessment into these broader programs will overtime accomplish two things for us: It will reduce the backlog of pesticides that we believe need a closer look right now but that we have not gotten to yet in terms of potential risks to endangered species, and it will serve to -- to block the increase of that backlog.

If we can keep up with that schedule, we obviously will not be adding to that backlog and just building a problem for the next person who takes my job in six years, which I don't want to leave people with that kind of problem, and then finally, by using these other kind of broader processes that, in some cases, are more well-established and, in the case of registration review,

is being established, we're hoping that we can ensure that we're affording the public the right level of participation because these assessments, and the decisions, and the mitigation would all be subjected to the existing or yet to be determined public participation processes in registration, re-registration, and registration review.

So, that's kind of the proposal. Bill.

MR. DIAMOND: The questions that we'd like to put to you to kind of frame a dialogue for the next 45 minutes or so go from the very specific. The very broad is basically what's the initial reaction, questions, comments, concerns about the overall strategic approach that we have just laid out.

Second question after we've chewed on that one for while is in terms of how does this approach satisfy the need for public participation in endangered species' assessments. We are going to build as much as possible in terms of the core program opportunities for participation, but there may be some unique aspects that we have to deal with, and then the last one is just for the last couple of minutes in terms of the specific areas that this group

wants to stay engaged in and discuss in a coming meeting.

Before we open it up, we're going to try and get some reactions from our federal partners. I appreciate the fact that Berlison Smith from the USDA and Clint Reilly from the Fish and Wildlife Service have joined us today, and I'll just ask them if they've got some initial thoughts, reactions, or perspectives that they can put on the table here, and we'll start with you, Berlison.

MR. SMITH: And these will be initial reactions since they didn't share their presentations with us before. So, with respect to USDA, we participated in the process that tried to develop the proposal in large part because we wanted to provide a perspective for the user community.

What we were looking for was something that ultimately would be practical, timely, and also would provide useable outcomes for -- from the decisions that were made in any type of revised scheme.

In large part, it was a observation of sort of a third federal party in -- in the discussions between the services and the EPA that the existing scheme that was being used was basically not working because it was a

mismatch of approaches.

In large part, as an observation, EPA was very much process-driven in its registration activities for pesticides, review either registration or re-registration; whereas, with the services oftentimes they were approaching any given consultation in more of a facts-based case specific approach, and so it was interesting --

(Tape 4, Side B.)

MR. SMITH: -- this with the agency and also with the services to seek this type of blend between it, between the various types of approaches. From that standpoint, without question, you've seen the complexity that was outlined in this presentation, and what we were looking at was balancing this complexity with a degree of efficiency in trying to make these decisions.

Ultimately, on an ongoing basis in terms of the public participation, we still see USDA having a significant role in serving the user community providing information. From time-to-time, there will be those discussions before they are able to -- to become public, where, within the federal family, we will have ongoing discussions in terms of what various cropping patterns may

be involved, and so we will continue to use some of the public participation mechanisms that USDA has with the user community and with the registrants to provide up-front input.

At the same time, we're also looking to utilize the outcome of this process, decisions that are made, and providing input into the bulletins and other mechanisms which EPA will utilize to try to communicate where specific risks may exist and how best to achieve protection of the species that are in question at any of those -- those places.

So, from that standpoint, I mean, broadly -- as an overview, that's what USDA will continue to do during this process.

MR. JONES: Thanks, Berlison. Clint.

MR. REILLY: Thanks. And thanks for inviting me to be here. One of the things that's happened over the last couple of years as EPA has been working through some endangered species issues is various levels of conversation among various roles and -- and players, and as much as anything else, I think that has led to some

common understandings that we've been struggling to achieve over a lot of years. The fact that you asked me to come, I think, is one piece of evidence. The fact that we have someone else from the service here sitting at the table throughout this whole meeting is another piece demonstrating to me that there is a new or common understanding of how we -- how we are intending to work together to try to achieve -- achieve some of these goals, and a broad reaction to the presentation, I guess, is I understand the presentation as much as anything else, what it -- what I feel like I'm hearing is that there's a long-term plan, long-term desire to incorporate examination of effects on endangered species, listed species with both Fish and Wildlife Service and (inaudible) is part of the ongoing process that EPA conducts rather than it being a reaction to litigation or a -- or a sideline note that has to be complied with when -- when somebody shines a spotlight on it, but to -- to, at some point, have that built into a process where it -- it's fundamentally part of the assessments that feed into registration decisions. By happy coincidence, that would be our goal, too, and I -- I think there is an opportunity not just to say that

that's a common goal but that that would be a way for some of these processes to succeed more effectively for users, as -- as well as for the people that are concerned about the protection of listed species, the constituency interested in some of our issues, and I guess in doing that it's -- it's worth noting a couple of key things, one, that that sort of long-term incorporation to -- to make such considerations part of EPA's process is easier said that done without question.

Among other things, the -- the numbers put up there is -- was a relatively conservative way to -- to look at some of those challenges to address the enormous numbers of possible combinations of active ingredients, and products, and species, and locations is a challenge that just doesn't work on the face of it, and in -- in light of that, the second half of the challenge, saying it's easier said that done is this is a long-term goal that we -- we recognize that EPA, no more than we can, is -- is going to have difficulties in turning on a dime in terms of changing a lot of processes, and between here and there there is going to be a continuing need to address the crisises (phonetic) as they come -- crises --

criseses, and so that's -- that's going to be interesting challenge, I -- I expect, as we try to work together in cooperative spirits towards long-term incorporation of endangered species examination, and yet handle the -- handle the spotlight challenges that -- that will need to be address that do come up, not simply because of things like a specific lawsuit in a specific area but because, as we go from here to there, periodically we're going to identify challenges where there's what appears to us a -- a real concern about a species in an area, at the same time, a real need for users to have some opportunities to use a certain kind of pesticide, and none of us know the answers yet, and we have to figure out how we're going to get through and have everyone comfortable. Those are never going to be easy things to work through, and they're going to be harder while we're still at the same time still trying to figure out exactly what the processes are.

As Berlison said, this is -- the working between the agencies has been, at some level, a classic exercise at fitting the square peg in the round hole and it's because we have slightly different missions and slightly different purposes we serve, and -- and each agency can

feel, I think, very justifiably proud about the systems they've had in place, but those systems were built for the purposes of that particular agency, and trying to crosswalk those two has -- has been an interesting adventure.

The counterpart regulations, I -- I hope most people are familiar with, we referred to here. That's -- that's a piece of -- it's an ingredient in accomplishing this, and if you're not familiar with that ingredient, you know, I hope you can become familiar, be willing to try to share that information with you, but it's an important ingredient to try to identify some means of -- of moving from point A to point B, but I guess I would -- I would hope we don't spend too much time focusing just on that proposal because, by itself, any new regulation, counterpart or otherwise, is not going to -- to -- to address these challenges that have been outlined in front of you.

Some of the -- some of the larger pictures that -- that were also described over the long-run over the next several years are going to be more -- more important steps, everything from some of the discussions here about

challenges from budget to the ability to identify new kinds of staffing and workforce capabilities to the abilities to coordinate between the agencies and address those needs as -- as we work from things like EPA's past practices of -- of addressing overall effects to environment and -- and figure out how to use that sort of a process to address a -- a classic question the Fish and Wildlife Service would be facing of, yes, but what happens right here with this species? Can we say that we have enough information to know?

So, fundamentally, I guess, reacting to this, it feels like I'm -- I'm glad EPA's working on this seriously. I've -- I've been convinced that the staff that I've been lucky enough to work with have been very interested in identifying ways to meet ESA requirements in a forthright manner that they've been facing and -- and very difficult challenge.

I think the Fish and Wildlife Service -- and -- and I guess I'd like to think I could be so bold as to say on behalf of Noah (phonetic) Fisheries, as well, has some renewed enthusiasm for the long-term prospects of seeing listed specifies appropriately considered through various

pesticide analyses and look forward to the continued discussions.

I don't think we've even fully identified all the questions that are going to be coming up over the next few years. I think we've got a lot better shot at cooperatively finding the answers as we discover those questions, though.

UNIDENTIFIED MALE: Thanks, Clint. I think we all agree that we certainly don't have all the questions on the table. This type of presentation is kind of a 30,000 foot strategic perspective, and I think that's important to work our way through that because it kind of starts to shape the framework for how we're going to answer all those detailed questions when they come up. We're going to open it up now, and I'd like to just open it up first -- in terms of the first question, are there any clarifying questions in terms of what we presented here, any ambiguity that you'd like to address before we get into the point of questions, reactions, or perspectives?

UNIDENTIFIED MALE: Yeah. This is a process issue, and if you could put slide 15, the chronolog --

chronolog -- chronological by action slide back up.

UNIDENTIFIED MALE: This probably isn't -- I got to get it.

UNIDENTIFIED MALE: Well, ac -- Artie, and this probably goes to you and some other folks, most of the triggers or the decisions points in here are triggered by formal decision processes that are active ingredient based, either re-registration decisions on new active ingredients or re-registration final reds.

The only other way that things have essentially been address from an endangered species process is through litigation historically. As we go forward in this process, how are new uses on existing products going to trigger endangered species issues or other things that are interim decisions like I-reds (phonetic) or those things that aren't final decisions, what does that do, and does it open up the total use package for that product with the addition of a single new use, or what -- how does that fit into a trigger for an initiation of this type of review, that's one question, and then the other has to do with grower liabilities at the end of the day once you all come up with whatever you've done, but if you can answer that

one first, then I'll come back to the second one.

UNIDENTIFIED FEMALE: I'll answer the first one first, is that what you meant?

UNIDENTIFIED MALE: Yep.

UNIDENTIFIED FEMALE: Okay. That -- that certainly is another piece of this puzzle, and in registration, I guess I intend that to mean both new actives and new uses of existing actives.

The question you asked about what happens when a new use comes in and that new use might trigger a concern for listed species. You know, we do go back and review the whole chemical again. What's the process there?

That's actually one of the questions where we have identified that question, but we don't yet have an answer. It was mentioned earlier we haven't even put all the questions on the table, and that -- that's certainly true. For those questions that we have put on our own table, I -- I would not sit here and purport to have all the answers at this point.

This is in its infancy of the thinking process, but it's -- it's an excellent question, one clearly that we have to grabble with.

UNIDENTIFIED MALE: And part of the context for the question comes from some of us are old enough to remember the old cluster analysis and a process that was done back in '86 and '87 to try to deal with a universe of pesticides which, at that time, Florida had the unique distinction of having more potentially impacted pesticide species combinations than any other state, and we attempted to look at this in the context of how to truly provide protection for the endangered species, and it wasn't necessarily related to pesticide use.

It was take the species, determine where the biological potential for interactions were, and then deal with that, whether it's pesticides or any other impact that would come forward from a task force type deal.

We worked with the U.S. Fish and Wildlife Service Office in Jacksonville, and other people, fortunately, we didn't have to sell mounted fishes and so many other things that other parts of the countries have had to deal with since that time, but through that context, most of the mitigation steps that the task force looked at and came up with, it looked like they would work, don't fit into nice, neat boxes as a national broad brush mitigation

process for dealing with this. Almost on a site-specific basis, you come up with a solution to deal with the pesticide whether it's grower easements, or conversation easements, or not using a pesticide during certain periods of time for protecting breeding habitats or whatever, and I would hope that whatever comes forward after the consultation process moves forward to mitigation steps that those types of activities are considered in addition to purely a broad brush geographical designation of species occurs in this area. Therefore, there was a potential risk. So, therefore, you got to do something.

I think it needs to be at a much higher level, which is going to involve a lot more people around the table discussing those mitigation steps that have traditionally taken place in the decision process as we've seen it to date, which brings me to the next step of my question, and one of the biggest issues that was raised in those discussions was what happens when you do everything right because these species tend to move, especially birds, and snakes, and some of the animals.

Plants have a hard time moving, but the animals can move into an area, and in some cases, through no fault

of the use restriction or mitigation efforts, you end up impacting an endangered species, and our biggest concern was a liability associated at the grower level through incidental take, and there are provisions under endangered species act to deal with that.

Is there any consideration in moving forward in either development of counterpart regulations or the process endpoints in the discussion for the agency of dealing with that issue at the grower level?

UNIDENTIFIED MALE: There was a lot in there. Let me just go to the last point in terms of the liability and any potential considerations during the counterpart regulation. Clint, do you want to try and address the issue in terms of any future consideration of grower liability issues in there as the counterpart regulations are developed?

MR. REILLY: I can try. Grower liability really is going to come from -- I'm trying to figure out how to do this without sounding like I'm getting too detailed in -- in weird pieces of ESA, but section nine is the part of the ESA that says you can't kill a -- kill a species, and grower liability would stem from that rather than from the

specific steps that are being taken by ES -- by EPA to meet section seven consultation requirements, and that this -- that may be known to most of the folks around here, the distinction between those two that a federal agency has to take steps to consult with -- with us about whether its actions might have an impact on species is separate from the basic law that says don't kill a listed species.

The reason that's important in -- in trying to at least provide a pseudo-answer to your question is for action to be taken to enforce section nine, there's a very different sort of scenario that would be considered than any action in -- in relationship to section seven. Section seven is largely challenged because you didn't do it, or you didn't do it right, or in doing it, you didn't consider some things.

Section nine and what a grower would have to worry about is -- is more of a classic sort of a situation: How can somebody prove that this particular step actually killed that particular dead bird?

I say all that because the real answer is prosecutorial discretion, and for anyone to make their own

judgment as to exactly what sort of discretion our law enforcement folks may or may not decide to take, I think it's worth keeping that sort of distinction in mind. I don't think we have any historical practice at all of holding particular growers accountable, and I don't think there is a good policy reason to try to look towards that sort of means of enforcing the ESA for the long-term benefit of species. There are obvious counter-examples that we could all come up with that we could imagine. You know, we'd say, well, gee, in this sort of situation, wouldn't you have to potentially -- but I think it's worth keeping that sort of distinction in mind in -- in terms of thinking through what -- what sort of policy judgments the service is likely to take, does that make sense?

UNIDENTIFIED MALE: Yeah, and I agree with you 100 percent on your answer, but it's a bigger issue than just ag pesticides because it's all pesticides, and there are a lot of pesticides that are used in areas that aren't as defined as ag areas which does have a much greater potential for incidental take issues, and it is something that's important, and I agree that it takes somebody going to the next step to force an enforcement action in that

standpoint, and it would be -- you would have the judgment of other things, but having experienced in a state that has a tremendous amount of litigation around these types of issues, just the mere threat of a potential for either not only take but harassment, which is also under the deal which is much harder to find opens a whole bunch of doors for issue at the grower level if this isn't done right.

UNIDENTIFIED MALE: Agreed, and I would like to think we'd point to past practice, and I answered -- I answer your question in the context of just ag growers, but I think the way I was trying to answer it, it would apply to all that.

There was another piece of what you were asking that I was also going to react to just for -- for what it's worth. When you were talking about the efforts in Florida to identify specific measures, times of year, very -- very local, site-specific ways to say how -- how can we use a pesticide in this place at this time in a way to feel more comfortable that's not going to impact listed species, I wanted to react to that to say that's been part of the challenge because that sort of way of thinking through is exactly what the Fish and Wildlife Service

normally leaps to immediately when we're dealing with a difficult consultation scenario with a -- with a federal agency or an applicant in any scenario that it feels like there's a -- this -- this is an action that we -- that could have impacts. What should we do now?

Our usual way of working through that is to get very case-specific and say, you know, if -- if you move the bridge a little bit this way, and you -- and you delay it a couple of weeks and -- and how specific can we get the facts to come to a solution here, that tendency is exactly what's driving EPA nuts, I think, at some level because that -- that sort of very close analysis is just almost impossible to do in 2,000 counties over all of the species and you start doing the numbers again.

So, one of the challenges and one of the things that I think has been going on is a way to recognize that at some level that makes more sense. The more we know factually, specifically, about the pesticide and about exactly which species it's affecting and in exactly what way and in exactly what times, and in exactly what locales, the more likely we can come to solutions that allow use of pesticides without fear that it's harming

pest -- harming listed species, allow that without having to do broad brush things like, okay, no more use for you in the state of California or -- or something like that, but it is -- it is a heavy investment of all the kinds of resources you can find to develop the kind of information to use those sorts of solutions, and I think some of the steps that EPA is taking is -- is intended exactly to lead to a greater opportunity to use those sorts of solutions.

UNIDENTIFIED MALE: Just -- just one quick point and I'll be quiet, though, but for existing products that are already registered, there is more leeway at the agency than for a brand-new active ingredient to involve stakeholders or actually in-use producers in those discussions because until that decision's made, we don't even have a seat at the table as a user unless we're invited by the registrant into this process.

The EPA can't even invite us in for potential mitigation steps at that point because of the way (inaudible). So, if the Fish and Wildlife Service wants to bring us in, we'd love to have you invite us into that process.

UNIDENTIFIED FEMALE: That sounds like a --

UNIDENTIFIED FEMALE: You can invite --

UNIDENTIFIED FEMALE: -- whole different --

UNIDENTIFIED FEMALE: -- us, too.

UNIDENTIFIED FEMALE: (Laughing) that's sounds like a whole different --

MR. DIAMOND: We've got a bunch of different questions here. I think I'm just going to ask Lois to talk about that issue in terms of the potential for earlier involvement by more people.

UNIDENTIFIED FEMALE: I want to clarify one thing before I give this to Lois because I think Clint may have left a mis-impression, we have been working very, very hard to get very geographically specific in the work that we do and to look at things like the biology, and the habits, and the habitat of individual species that we're looking at in making determinations as to whether or not a pesticide may affect that species, and if so, what the appropriate mitigation might be, probably not to the level that the Fish and Wildlife Service can look at a construction project's affect on a -- on a species, you know, a project that's status in terms of its geographic location, and you can pinpoint where it is.

One of the -- one of the issues we have in getting more specific is that it's very difficult to find out information about where a particular pesticide is used and where particular crops are grown, but to the degree that we can do that, we have been doing that, and I just -- I didn't want Clint's statement about how -- what they're trying to do drives us nuts, which it does, I didn't want that to be misconstrued as -- as us going back to our old schemes of saying you can't use something in a county and certainly not you can't use something in a state, and some of the internal things that we're looking at to try and refine our processes, our geographic-based systems that will let us get even more specific in terms of where there might be a particular impact to a species from the use of a pesticide. So, I just needed -- I needed to clarify that.

UNIDENTIFIED MALE: Thanks. Lois.

MS. ROSSI: Well, Dan, your -- your point is well-taken, I think, in re-registration. Is this thing on?

UNIDENTIFIED FEMALE: Um-hum.

MR. ROSSI: In re-registration, you have a public

process that has now been formalized, and it's out there, and there's opportunities for stakeholders, and registration doesn't exactly have that complement. Although -- and it actually is important because when you're registering for like particular new active ingredients where there could be like a reduced risk, and you're actually registering that maybe before the pesticide that it may take use away from it goes through this endangered species review, you could be putting it at a disadvantage from getting market penetration.

So, I think that's one thing you have to -- you have to take into consideration. So, for new chemicals, there -- there isn't the compliment except, you know, with the -- with -- at this point. Again, with the -- we can go through the routine questioning of the registrant as we sit there, you know, looking at mitigation measures to see to what extent they have consulted other stakeholders, growers, other public interest groups.

For new uses, it's a little bit different, though, because it is an already registered pesticide, and if, in fact, you are considering obviously the endangered species problem, impact for the new use and then if the

chemical hasn't been looked at, you may even do it at that point. I -- I have no idea. I mean, that hasn't been fleshed out, but -- but that kind of can be a more open process because it's an already registered pesticide. So there are things that could be done to get consultation with other stakeholders before a decision is -- is crafted on that, and you know, we can obviously take the -- the -- the practices that we used in the public participation process with conference calls and all that kind of stuff to open it up a little bit.

UNIDENTIFIED MALE: Thanks, Dr. Holm.

MR. HOLM: My question has to deal with whether the agency has considered any acreage limits on -- on -- on doing endangered species evaluations. I'm here among other people here that are representing specialty crops, and of the 500 or so crops that are -- are listed for EPA potential registration, only 30 of them are considered, you know, major crops, and the rest of them are minor or specialty crops, and many of them are involved in, you know, 10s or 100s of acres.

So, it would seem that there would be a lot of resources extended to do some of these very specialty crop

registrations or evaluations for endangered species, and on top of that, we may be complicating the situation, but right now we have a proposal -- IR-4 has a proposal to the EPA to add an additional -- up to an additional 500 crops to the current crop grouping concept. A lot of these are ethnic, tropical crops.

Many of them are being grown in areas, you know, for Asian markets and so on. They're truck -- truck crops. They'll be grown on one or two acres on -- in road-side stands. So, I'm just wondering, with that kind of scenario, does it seem more likely to maybe exclude from evaluations some crops based on acreage and -- and so on to avoid, you know, that resource drain?

MS. ROSSI: That's a real good question, and you're right, it is a resource drain. The issues -- the issues, I think, that we face in just trying to blanket exclude something based on the -- the acreage that the crop might be grown on is probably best illustrated if you're looking at an endangered plant that might be very close to where even two acres of something is treated with a product that could have an impact on that plant.

So, just excluding based on acreage is not

something that we think is a wise thing to do. I will say that once we have determined that the toxicity of a pesticide could have a potential impact on a certain type of species and there may be some geographic proximity in the use of the pesticide and the species, one of the things that we have been using and hope to continue to use to characterize the -- the level of concern, if you will -- the degree to which we're concerned, is the acreage grown in a given watershed or a given area that might impact that species.

Again, it's not made -- it's not used to make a clean cut in terms of yes or no, but if the answer's yes, we have a concern, we then do try to get that kind of information to characterize how big the concern is.

If you're looking at a species that has a very wide range geographically and you're looking at a crop that really is only grown, you know, 10 acres in three different counties throughout that wide range, the concern would probably be less than if you were looking at a crop that was grown throughout most of that range, and it -- you know, much higher density near where the species might be.

So, while it's a consideration, it -- we've not looked at it as kind of a black and white. I just don't think -- don't think that would work for us.

UNIDENTIFIED MALE: Thanks. Carolyn.

MS. BRICKEY: Yeah. I guess I'm not sure exactly how to engage in this issue. The -- this framework seems incredibly skinny to me, and I don't know what to do with it exactly. I mean, I don't think it's bad, I just don't know what to do with it because I don't know where -- you know, when you say you're going to incorporate the endangered species decision-making into this bar chart up here, I don't know how or when you're going to do that, and I agree with -- with Dan, a few of us do remember the cluster approach, and there -- it had its good points and bad points, but I'm hoping that, you know, you're -- you know a lot more than you're saying about where you're going with this because I can't tell a hell of a lot about what it means right now.

I think, you know, the numbers you showed us were daunting in terms of the -- multiplying the scenarios, and the species, and so on, and so I look up there at these numbers, and I don't know if I'm adding on decisions to

those numbers up there in those little boxes or -- I don't really know what I'm doing. So, I -- I have trouble figuring out how you want us to engage.

UNIDENTIFIED FEMALE: I think --

UNIDENTIFIED MALE: Let me -- let me take that one on. The first thing that I think the agency needs to figure out is how are we going to get into compliance because I don't want to be working for four or five years on a strategy to get into compliance only to find out that the entire stakeholder community thought that you were using the wrong processes -- we were using the wrong processes.

So, what I'd first like to get feedback on is the general approach of how we plan to get into compliance, which is to in -- incorporate endangered species assessments into our existing and soon-to-be existing programs, registration, re-registration, and registration review. Then, I think, as we get more sophisticated in our understanding of -- and we've done a little bit of this in a -- in a workshop a few months ago, that talks about how we do the assessments and you get a greater understanding of how we do the assessments, I think we

then can have more discussions somewhat like the carrot discussions were around how we do assessments for cumulative risk or how we do assessments for drinking water. Then we can engage stakeholders on those issues, but I really don't want to head down a path for how we're going to get into compliance, what approach we're going to use, which programs we're going to use before I have some sense as to whether or not there's a large degree of acceptance to that or not.

I do think we've done some work to education stakeholders about how we're going to do these assessments. We haven't done enough and I don't think you've done enough to learn it. It's -- we spent a day at it about three months ago, and it was -- you know, it was tough (inaudible) like many of the carrot meetings we had that were day-long, it was hard to really sit there and take it all in.

A number of you were at that -- I think that we need to -- we need to think of other mechanisms to do that. It's costly for us. It's clearly costly for -- for all of you, but I think the first thing we're looking for feedback on is there a general acceptance with this

concept of incorporating endangered species assessments into our existing programs, and -- and if we do that, you saw how we'll do it. We're going to do it in the reds that are left to be done to the extent we can. We're going to do it in our registration review process, and we're going to do it in our registration process. End of the day, it's going to take 16-odd years to get through all of the chemicals, that's -- that's basically how we plan to go from the -- where we are today until full compliance.

MS. BRICKEY: So, you're looking to develop a decision tree so that you can figure out for a new AI or even for an old one, by going down your decision tree, you'll get to a point where, yes, there are endangered species issues, or no, there are not, is that the plan?

UNIDENTIFIED MALE: In each individual decision.

UNIDENTIFIED FEMALE: We actually already have decision points like that that are established.

MS. BRICKEY: Well, I know you don't want to run this program by litigation and I certainly support that, although, as a lawyer, I kind of like litigation, but --

(Laughter).

MS. BRICKEY: -- how do you -- you know, without looking -- going spec -- species specific with your triggers, I mean, how -- don't you have to end up doing an awful lot of work that, in the end, is useless --

UNIDENTIFIED FEMALE: We -- can I address that?

MS. BRICKEY: -- expensive?

UNIDENTIFIED FEMALE: Incorporating the assessments into these broader processes wouldn't necessarily change how we do the assessments. We still would be looking to that baseline risk assessment to let me and my group know whether a particular chemical hits triggers for mammals, fish, birds, insects, plants, and that's what we would focus in on. We're not --

MS. BRICKEY: So, it would be like you're a separate division. This is how you're --

UNIDENTIFIED FEMALE: Yeah, feeding -- only it's a branch -- feeding -- feeding into that. Where's -- where's the little pointer thing? See, now my new boss, Bill Diamond, told me I should put divisions on here.

This is basically the environmental fate and effects division assessment.

MS. BRICKEY: Okay.

UNIDENTIFIED FEMALE: This is currently what my branch does, and what we're talking about here is continuing to do that in this -- in this unit but, again, doing it earlier in the process and coordinating with this screening level assessment so that by the time it gets down here, we're all done. The way that it works right, these people do their whole assessment. It comes down here, gets like maybe over to here, and then somebody goes, oh, we have endangered species problems, fix them.

So, it doesn't change how we do the assessment, it changes when we plug into the process, how we coordinate internally to make that process more efficient so that when it comes to the end of the day, we've all done our work and we're not coming in at the tail-end.

MS. BRICKEY: Okay. One more question, when you're doing -- you've already done some worker capacity analysis on how many people it's going to take to do x-number of assessments in how many years; right? Could you give us a little feedback about that?

MR. DIAMOND: We've done -- we've done some initial ballpark estimates with a lot of assumptions built in, and the assumptions are the number that we might have

to do that would hit the triggers, the difficulty, how we're going to work the new process that we're establishing with the services and how we can meet the new timing requirements that are established by fee for service.

So, what we've got is a ballpark, and we've got a significant investment in that, but just as you heard with the registration review process this morning, we are working with our counterpart divisions to try and pilot test some of these things to do a reality check in terms of what it really is going to take, and that's why we're thinking over the next couple of months or year in terms of trying to actually do some of these things, we'll have a much better handle on the demands in terms of how well this will work or what the resources available will be, but right now I think we're just kind of ramping up and learning as we go, and we will feedback that into the mechanism as we get there.

As Jim says, we're into this for the long-term, and we want to learn as go. Dr. Golden, Nancy?

MS. GOLDEN: Yeah. The registration decisions coming out now have specific language that referred to the

formation of the endangered species program, but like you were saying, not necessarily in evaluations since there's a backlog.

I just wanted to get some clarification, I'm not sure exactly how that backlog fits in with the chronology you've presented. Is that part of the registration review process? So, the thing's coming out this year, it could be 15 years before there is actually an evaluation; is that correct?

UNIDENTIFIED FEMALE: According to this scheme, yes, if it has been through re-registration or whatever other processes it needs to go to, the next time it would (inaudible), if you will, unless it is one of those specific circumstances down at the bottom would be when it came up for registration review, according to this scheme.

MS. GOLDEN: Okay. Just a suggestion, you might want to include that kind of language in the decisions, themselves, because there is an implication. When you read those it seems like, well, they're forming this program, and they'll be addressing this in the near future, and as it -- it's kind of irrelevant now if it's going to be that far off in the future.

UNIDENTIFIED FEMALE: Yeah. I think -- I think you're right, and one of the things that we've been talking about among ourselves is -- well, first off, when you say that most -- most of that language that was put in there was put in there when we thought we were just going to still be running our little separate program and we'd never managed to integrate into these other processes. So, it was accurate at the time, I believe.

MS. GOLDEN: Okay.

UNIDENTIFIED FEMALE: But we have been talking about how we can better articulate in some of these documents coming out exactly what our plan is for addressing the whole gambit of endangered species issues for that pesticide. I appreciate your observation on that. It's a -- it's a very good one, I think.

UNIDENTIFIED MALE: Julie.

MS. SPAGNOLI: Some of my -- oops -- questions have already been answered, but it's back to the general process, just to get a little more clarification on -- and as far as like these unusual circumstances or special, specific -- would that generally be based on like adverse effects or some kind of reports of adverse affects or

allegations? I'm just wondering what -- what do you foresee as those specific circumstances?

MR. DIAMOND: We haven't specified the criteria because we are still working through. There's obviously certain things that will influence us. As (inaudible) indicated, we want that to be as small a subset as possible, but yeah, issues in terms of new information that shows significant harm would be something that we would consider in terms of bumping it up from the chronological type of approach that is the base of this concept.

UNIDENTIFIED FEMALE: So, similar to -- you know what, back to kind of our discussion on registration review that you would not necessarily have to wait for registration review if there was information that indicated you needed to look at that segment separately as opposed to the whole review process. I -- I think that goes along with what we were saying with registration review that it doesn't -- registration review doesn't preclude any of the other programs or processes by the agency.

MR. DIAMOND: Right.

UNIDENTIFIED FEMALE: Okay. Then specifically, you know, and I think Dan kind of asked the question with a new use. I assume with a new use that the initiation, the screening level assessment would then be for that new use -- in looking at that chemical for that use, that would be that level of assessment, but if you're looking at -- for an active ingredient either for registration review, and in particular, re-registration or registration review, that screening level assessment, now is that just looking at effects of the active ingredient, or are they also -- and I guess looking at to come to another term we had from this morning, the easy off ramp, does that also look at just -- there are certain uses that just don't need to be considered further, and they just kind of fall out of that screening level assessment, even if the chemical may hit certain triggers, and I guess I'm looking at what -- what is screened in that screening level assessment, is it just the chemical, or is it also the uses, and so, you know, do some of them fall out at a screening level as versus just the chemical?

UNIDENTIFIED FEMALE: I think some of them could fall out. The screening level is generally in the course,

as you mentioned, of -- of existing chemicals based on data from the active ingredient, but in re-registration, for example, the product labels are looked at, the specific uses that that active is registered for the rates that it's registered for. All of that is considered in doing the modeling and the assessment that leads to a conclusion that a particular kind of species either will not be at risk or could be at risk.

Then the species specific assessment -- and I think Jim's right, clearly, we need to have more sessions on this. The species specific assessment then would actually look at the product labels, what the specific rates are, where that crop might be grown.

So, it gets more specific about the screen screened out. There may be, through discussions of my group, and the science reviewers that are doing the screening level assessment, opportunities to screen out certain products at that stage. If not, we hope that we would catch it in the species-specific stage, and let me give you an example: An active ingredient -- and I don't mean to pick on anybody, but let's say an active ingredient that is used in fly paper as a pesticide once

the fly gets stuck to the paper was determined to be toxic to a plant -- it has plant toxicity when you spray it, but it also has this effect on the flies, when that product is used in fly paper, it's real unlikely it's going to have an impact on an endangered plant.

So, it's a specific kind of product that we could put off the table if we were looking at endangered plants, if that -- if that was the issue. Now, that's obviously an extreme and silly example --

UNIDENTIFIED FEMALE: No, it's not because I think, you know, for any active ingredient, there may be a whole chunk of uses that can just kind of go on that --

UNIDENTIFIED FEMALE: Right.

UNIDENTIFIED FEMALE: -- the easy off ramp and so that you don't have -- I mean, I'm looking at it from a resource --

UNIDENTIFIED FEMALE: There very well may be --

UNIDENTIFIED FEMALE: -- priority standpoint --

MR. JONES: Put let me -- let me -- I need some advice; okay? What -- what -- and I don't want to lose the time without feeling like we got some sense -- and I'm not sure that we -- it's a very simple question we're

asking you your advice on.

There are a ton of complicated questions associated with endangered species, and we're -- I don't think we're ready to engage them right, but we will. What we're looking for -- there are a lot of ways in which program managers could get into compliance the 1200 pesticides that are currently -- we need to get into compliance for. We could do it alphabetically. We could do it over the next 30 years. Somebody -- we could do it by species. We could do it by litigation, not my option. There are a lot of different ways.

What we have put forward is an approach to get into compliance. We've told you how long it will take, and we've told you generally what programs we would use to do that, and we're looking for general feedback or specific feedback of Jim that is too fast, Jim, that's too slow, Jim, you should be doing a species, Jim, stick to litigation, that's what we're generally looking for, or my favorite answer would, of course, be I think you guys sort of are following what I would do if I were in your position. I think that's a responsible way to go. I'd give you this -- you know, this little tweak or that

little tweak, that's sort of the question we've teed up for some advice.

Clearly, there's the need to engage all of you and others on a lot of other issues associated with this program, and we are committed to figuring out how to do that, from how we do our assessments to how we engage in consultation and all of the other attributes that are important to understanding how we're ultimately going to implement it, but really the question before the PPDC is pretty simply but actually quite important to us because we do not want to go down some path and then have you all figure out over five or six years, what on Earth are these people doing? That's not really how they should have -- that's not the program I would have designed.

That being said, anyone want to give us some advice on that question? Erik.

MR. NICHOLSON: I do. I don't think this is going to do it at all. I think what you're going to see is a whole lot of litigation because your time frame is way too slow, and from I understand the environmental community is doing, I think you all should do the same is review the toxicity of these pesticides, prioritize them

as per toxicity, and prioritize those.

By driving it by registration date, I think you're missing the boat, and I think you're going to see a whole lot more lawsuits against the agent -- the agencies before you finally get around to taking the decisions that need to be taken. Okay. Jay.

UNIDENTIFIED MALE: I believe that this approach is commonsense and well thought out, and as we've said in our comments to the docket on the counterpart regulations, it makes a lot of sense. There's plenty of evidence to say that what has been litigated so far has been procedural.

What you're responding here with is a procedural solution in terms of the counterpart rigs and the process generally that you've outlined, and I think, you know, once the general public knows more and more about and particular tax payers, the only admonition will be to the respective agencies, the services and EPA to let EPA do what it does best, and again, to the extent that those of us have the ability to lobby both the administration, in general, and the Congress specifically on behalf of tax payer interests, we would like more and more efficiency

from our Federal Government, but in this case EPA knows more about these chemicals and will always know more about these chemicals, and the services ought to defer more than they have in the past of the agency and get on with, you know, implementing the process that is already there, but the dots now are connected with counterpart (inaudible). Beth.

MS. CARROLL: I just wanted to say that I think you're on the right track. I, obviously, would like to see things move more quickly, too, but I recognize there is resource constraints, and I just also wanted to bring up in response to some of the comments that Carolyn made, I do think progress is being made, and I do know that you're going to get information on the IMS database and Nature Serve in June which should push this forward, you know, more significantly.

MR. JONES: Patti.

MS. BRIGHT: I have a couple of questions and a couple of comments --

(Tape 5, Side A.)

UNIDENTIFIED FEMALE: -- there's currently a decision by us that the pesticide may affect the listed

species. If we can't say there will be no affect, we're required to move forward in consultation with the services, and the counterpart regulations would tweak that a bit, but currently the requirement is is if we -- if we cannot say there is no effect, we have to consult.

MS. BRIGHT: And how many people will you be hiring to do this?

UNIDENTIFIED MALE: Very good people.

MS. BRIGHT: How many?

UNIDENTIFIED MALE: Right now I think we've got -- how many do you have on your staff --

UNIDENTIFIED FEMALE: I've got seven on staff and --

MS. BRIGHT: How many will you be --

UNIDENTIFIED MALE: We've got about seven on staff --

MS. BRIGHT: -- hiring -- how many new people, though, will you be bringing on to do this project?

UNIDENTIFIED MALE: Right now I think we're authorized to hire an additional 10 people in our organization.

MS. BRIGHT: Um-hum.

UNIDENTIFIED MALE: There will additionally be other people hired in EFED to do some of their things, and I don't have what the number is, but a lot of those people that are already there will be doing some of those -- that work.

MR. JONES: And I do expect, Patti --

MS. BRIGHT: And will these be wildlife ecologists?

MR. JONES: -- that in the registration review program -- I could be wrong, and our pilot on registration review will inform this that we talked about this morning, but I expect that likely the bulk of the work done by our environmental fate and effects divisions, which is a division of nearly 100 people will, in registration review, involve endangered species; whereas, currently right now it's basically core ecological risk assessments that hadn't been done before --

MS. BRIGHT: So, EFED will be --

MR. JONES: -- but those will all be completed.

MS. BRIGHT: -- so, EFED will be doing some of this?

MR. JONES: Oh, large -- they will be doing a

large part of this work.

MS. BRIGHT: So, you know, this kind of reminds me if you ever read the time management books, they say, well, if you make the excuse that you don't have enough time to do it right the first time, where you going to find the time to go back and redo it? If you guys haven't been doing this for 20 years, I just find it a little hard to believe that now all-of-a-sudden EFED is going to have the expertise, and the time, and the resources to do that.

When Berlison was talking about the process between Fish and Wildlife Service and USDA, he was mentioning the fact that there seems to be a mismatch there -- or excuse me, that that process between EPA and Fish and Wildlife Service, he was saying that there seemed to be a mismatch there because EPA is very process-driven. The Fish and Wildlife Service is very fact-based driven. Everything I'm hearing here, the things that Dan said, the things that others have said about wanting to get this very specific -- you know, talking about kind of the clustering in Florida and the need to be able to look at specific situations and how you mitigate those, as well as the comments that Julie brought up about if you're going

to have this off ramp, it needs to be -- you'd need to be able to look at specific situations.

That is exactly what Fish and Wildlife Service is set up to do. Those guys are the experts. They have the ecologists. They have the biologists. You know, I've sat in this meeting. I've listened to your talks on ESA. Multiple times you guys have noted publically the fact that one of your problems is you don't know where the endangered species are located. That's not something that I would expect that EPA would know, but I would expect Fish and Wildlife Service to know that, and I know that the Fish and Wildlife Service knows that.

So, you know, I -- I could go on for an hour. You guys have heard this. I think you -- you heard me at the last endangered species workshop. As you said, there was a lot of information that was put out there. It's hard to get your arms around that, but I would strongly suggest that you guys go back and re-read the public comments because I've read some of those letters, and they are very detailed, and they are very specific as to what the stakeholders' concerns are.

I really think it is important for you guys to go

back and look at those things. You know, Jay just said that he thinks that if this gets out there to the public, the public will want the EPA to do what EPA does best, and I agree with him, and I think if you look at the comments that's what the public is saying, they want EPA to do what EPA does best, which is -- which is look at pesticide registration. They're not wildlife experts. Fish and Wildlife Service are the wildlife experts, and I think if you look at your comments, that's overwhelmingly what the public is saying.

UNIDENTIFIED MALE: Jim, I would like to clarify --

UNIDENTIFIED MALE: That's not exactly what I meant to say.

(Laughter).

MR. JONES: Hang on. Hang on. Everybody will get their chance. Patti, what I didn't hear is sort of your advice as it relates to what processes we use to get into compliance. I heard you say you didn't think we had the horsepower, I heard that, but I don't think I heard your --

MS. BRIGHT: Or the expertise. I think that the

-- I think the current process is not broken. It's just not being used properly. You have the experts who are available to say that the service should defer to EPA is not the way this process should be working. You guys are sister agencies.

As Berlison said, you've got this federal family. You're going to be consulting with each other. You guys do consult a lot with USDA. If you're dealing with endangered species situations, then you should also be consulting equally with Fish and Wildlife Service.

MR. JONES: We are. That's not the issue on the table, but thanks. Larry.

MR. ELWORTH. I'm actually going to talk slow compared to Patti --

(Laughter).

MR. ELWORTH: -- that's interesting.

MS. BRIGHT: I had to get it all in.

MR. ELWORTH: That's good. I -- I thought that the comment that -- that -- if you go back to slide 14, I thought something that was very helpful and what Artie pointed out was that what -- if I understand correctly what you said, that at least part of what this process

does is allow the agency or force the agency, depending on your point of view, to look at these issues much earlier on, not get further down the line and go, oh, crap, we got to come back and catch up on this.

I think that's the right way to do this. I think that was something that was -- wasn't happening before, but I think it also points out the fact that the agency hasn't been utterly and totally ignoring the issue of endangered species through the history of the program. I mean, it's -- EPA has had some help from the ag committee on how it approaches those kinds of things in the past, and in terms of where we are now, it might have been perhaps better if the ag committee had taken a longer view of what the effects of those actions would have been, but nonetheless, I think that that one piece of it is the right way to go about this.

I also would -- would point out one thing that -- that happens here, and I don't know for sure that this happens at Fish and Wildlife Service. This kind of public input into this process is really, really important, and I would hope that -- that -- that the people at the service have an opportunity to participate in kind -- sessions

like this to see the kind of public input that can be -- can be involved in -- in setting up a program and running it. I think it would be very helpful, and I think I would welcome not just you being here but people who are going to interact with EPA to hear from this group and others, along with people from the EPA, how the program could or couldn't work effectively.

MR. JONES: Thanks. Larry -- Lori, I'm sorry.

MS. BERGER: I have a comment and a question here or vice versa. Have you done any cost analyses, you know, doing it primarily with the EPA doing the risk assessment versus Fish and Wildlife, or what kind of cost studies have been associated with this whole process, anything?

MR. JONES: Let me just be clear that we're -- we're operating under the existing rules right now which involve if -- it may affect findings made by the agency. We, under the existing rules, consult with the appropriate services. That is how we're planning on operating. If those rules were to change, which they are proposed to change in the counterpart rule that -- that -- the time and point in which we would -- or the standard for when we would consult would change, but we're -- we are not -- we

are not attempting to figure out in the office of pesticide programs whether or not that is the optimal way to go or there ought to be a different way. Those are the rules, and that's the way we're -- we're operating. So, we haven't tried to figure those things out.

What we are trying to figure out is what does it cost to operate under the existing rules? That's important for us to understand how much it will cost us to do that, and how much would it cost to operate under potential changes in the rules, and part of what our pilot work right now in endangered species is trying to figure out is what does it -- what does it take?

How much -- how many resources will we need to be in compliance given the number of chemicals we need to do what is the current rules or perspective future rules mean for us?

MS. BERGER: Okay.

MR. JONES: So, we're -- we're engaged in that exercise right now.

MS. BERGER: Okay, and then the other -- I just had a comment that I do believe that EPA does a very good job on the risk analyses, and my perception -- and I -- I

might be wrong on this, I don't see their purpose as to be just registering things. Part of that is the risk assessment process.

You guys might be or the wildlife folks might be keener on the location, but from an organismal standpoint, I really do believe that they have established a very good track record of looking at the broader picture and where the sister agencies can work together more effectively is -- is taking the body of information that they develop, and they may need to be working on their system better, and I -- I think you guys are on the right track, but working with you guys on specific locations, on mitigations in that -- in that standpoint. So, those are my comments.

MR. JONES: Clearly, there's -- there's an opportunity for us to have some discussion around it some point in the future the -- what our assessments involve. I think that that's obviously something people are interested in hearing more about.

Julie, did you have another --

MS. SPAGNOLI: Yes. I had to ask a few of those clarifying questions --

MR. JONES: Sure.

MS. SPAGNOLI: -- just so that I could understand the process a little better, but I do think, you know, the process as proposed makes a lot of sense in that it's very similar to what we discussed with registration review that you need a systematic way of approaching it, and I think the chronological approach is a good systematic approach. Understanding that, it does not preclude that agency from taking actions if -- if deemed necessary, the same issue that's been brought up with registration reviews. We need to have a logical, predictable way of looking at this, but it doesn't mean that that's the only way it can be looked at.

So, I think that -- you know, I think this then is a very good approach because it says, okay, for most cases, this is going to be a good, logical approach, but we always have the opportunity to -- to address a problem, should it arise, and the other part was, you know, that it's an efficient use of resources looking for those ways of the easy off ramps where they're appropriate because then, obviously, it's just a more efficient use of resources.

So, I'd say, you know, based on those two aspects, I think that it's a good approach.

MR. JONES: Rebeckah.

MS. FREEMAN: I'd just like to echo -- echo that we do think that you're on the right track given the unfortunate circumstance that has put you in the circumstance of having to comply with a heck of a lot of deadlines from a lot of different directions.

You are looking at this from the perspective of having to meet a lot of obligations from a lot of things that have been either forced upon you or you haven't had the appropriate resources probably to address as thoroughly as you would want in the past.

It's -- it may not be the perfect system, but certainly giving the unfortunate circumstances that you're under, it is a circumstance that should meet the needs, and we do believe that, at least from a perspective of my -- the people that I represent and the farmers and the stakeholders out there, we do believe that you have and do continue to look at endangered species issues that are you are competent and have the expertise, especially in accessing other information from other agencies and

sources that you might need to complete those evaluations.

If you need to improve your process, please do so, but we do believe you have the expertise and the competency to do that primarily because your first challenge as the environmental protection agency is to protect the environment, and the secondary will be -- the second charge that you have in the office of pesticide programs is to efficiently and effectively register pesticides so that sort of the notion that you are not out there protecting the environment, including endangered species and species not endangered is simply, you know, not -- not the perspective that my stakeholders that I represent come from.

So, we applaud your efforts, and on the second note, we do encourage you to look at the comments that have been turned in on the proposed regulations. There are substantial numbers out there that do think you're competent to do so.

MR. JONES: Anyone else? Oh, I'm sorry. Sue?

MS. HAYSON: Oh (inaudible). You know, in a perfect world, you would be in the hole, you know, and it would be great if it could all be finished tomorrow, but

again, I just want to reiterate what other people have said.

There are resource constraints. You have to attempt to approach this in the most efficient way possible, and I think that what you've presented, more or less, you know, is about as -- as good as it's going to get just because of the reality of all of your competing obligations.

I think some people here have, Patti's comments notwithstanding, are having a hard time with this issue perhaps because they don't understand what a typical -- what the typical requirements are in terms of data, what kind of ecological, environmental fate risk assessment is actually done routinely.

There is a lot of expertise in the agency, and -- and I see the agency's expertise fitting in pretty darn well with the services in terms of being able to compliment each other and certainly no reason for the services to be doing the toxicity assessments or whatever when the agency, first of all, has some very good data, well controlled, high quality, all of that.

So, I mean, I think it's -- I think that the

resources of EFED knowing that there's going to be an actual use for that risk assessment immediate, I think -- you know, I think that that makes them more efficient in a lot of ways, but you know, I think you are on the right track.

I think you're on about the only track that makes a whole lot of sense because anything else is going to require so many resources just even get up and running. If you're going to make a selection, oh, what we have to do first, well, that's an enormous task in and of itself.

So, I think -- I mean, I think this is the way to go. Obviously, if people decide to sue, that will just delay an orderly outcome, I think, you know. So, I think you're doing -- I think, given your resources, given your mandates, this is as good as it's going to get.

MR. JONES: Dennis.

MR. HOWARD: I guess I'm -- I'm with the majority, I think, of the comments in -- in believing that the approach that you're taking is sound and it makes sense, but coming from a major/minor crop state, I'm also -- I'm also concerned to some extent that if the agency is going to make risk assessments and mitigation that will

keep it out of trouble with endangered species problems, it's probably going to err on the side of conservatism rather than hedging the bets on the user side of things.

So, what -- what I would encourage the agency to think about is mechanisms that -- for those areas where some refinement in the risk assessment based on localized input would benefit that -- that you try to consider a mechanism to -- to take into account that kind of refinement.

MR. JONES: Thanks. Okay. That was helpful. Thank you very much. The issues that I think are really very difficult in a discussion around this is that there are so many issues that are a part of the endangered species discussion.

It is very challenging to get us all focused on what -- at this point, the agency was looking for advice, and I think that actually in the last 20 minutes I got a fair amount of solid advice, and I -- I -- even though most of it was in the I think this approach is the right way to go, I certainly recognize that the perspective that you're setting yourself up for more litigation, we've got to figure out how we can minimize that. That's a logical

observation to the approach we put up, but I feel like we did get the kind of input that we were looking for on this particular issue.

There is no doubt on my mind and, I think, in any of your minds that there are other very important issues associated with endangered species that it would be useful to have the PPDC engage on, and I'd like for you to be thinking about that between today and tomorrow when we spend time talking about future topics about what they might be.

I think the -- the field implementation, to give you some ideas, might be an idea. The -- how does EPA do its assessment may well be an idea, and you may have some other ideas around endangered species issues other than what approach are we going to take to get ourselves into full compliance that would be useful for a future discussion. So, we will definitely spend some time tomorrow on that particular issue as a future topic, and I'll be looking for your insights into what you -- what you think the -- the broad but not too broad ESA issue would be useful for us to engage in as a dialogue committee.

All right. We will take a 15 minute break. I want to thank the panelists, and we'll be back at 20-of.

(Whereupon, a brief recess was taken.)

MR. JONES: For those of you who are from out of town, I apologize we don't have quite the cicada presence that I was hoping for all of you, but our very clever creative funding staff has made up for it, and we now have some cicada at the table.

UNIDENTIFIED FEMALE: Well, anybody who wants the experience can come to my house.

(Laughter).

MR. JONES: Okay. Start it off -- start off with our -- start -- actually, we are going to finish up with our last topic for the day. This -- this is an area, as I mentioned in -- in my opening remarks, in the 10 years I've been in OPP, not a two or three month period goes by where there is some request to the agency to consider or allow environmental -- what I -- what I'm called or we've called environmental marketing claims. There are a lot of different terms you can use to describe that, and I thought -- I thought that it's the kind of issue that is

very appropriate for getting broad stakeholder advice before the agency makes any -- any determination, and so we brought this issue in a very shorthanded way -- not shorthanded but in an abbreviated way at the PPDC the last time.

We then created a -- in our PPDC forum, we put -- posted a paper and asked some questions, and for the meeting today we have a panel that Lynne Noos (phonetic), who brought the issue to us last time, is going to facilitate this afternoon. So, with that, Lynn.

MS. NOOS: Okay. Well, as Jim said, we did put some questions on the list serve. We didn't ask -- asking for responses from the members of the PPDC panel, and that was in response to Jim's closing of our meeting at the last meeting, where he requested that folks go back and think about whether -- how the inclusion of claims on pesticide packaging might result in positive environmental benefits, and -- and that was part of meter for would we want to consider using a pilot or putting a pilot in place or not. You know, are there positive environmental benefits that will balance the resources it will take us to develop a program.

To frame the discussion, we did put the questions on the form. We had about five comments. Some were highly favorable, some were very negative regarding the (inaudible) question.

So, today we're going to have three panelists. Paula, would -- or sorry -- Julie Spagnoli is going to go first from Bayer. Paula from Scotts (phonetic) is going to go second, and then Mary Ellen Setting is going to speak from the State of Maryland, and I would like you to hold your questions until the three panelists have talked.

They should probably have pretty brief presentations, and then we can do any clarifications from those and move forward with just an open discussion. Julie, you want to start?

MS. SPAGNOLI: Well, I -- I originally brought this topic to the PPDC looking at it from the standpoint of label claims, and based on some past experience, looking at previous experience about 12 years ago, I worked on a workgroup with the Federal Trade Commission.

We worked on the environmental marketing guides, and I think when I approached this, I wasn't looking at it so much as to environmental marketing claims per say

because I think those were pretty well, you know, hashed out and -- as we looked at it with FTC, but looking at the approach that we took as far as what kind of claims would be looked at as not being false and misleading and being useful to, in particular, consumers in making product choices, and you know, what they concluded from the FTC (inaudible) was essentially that claims of general environmental benefit were generally considered deceptive, and that, you know, unqualified claims that -- and I'm going to read right from FTC's saying, "Unqualified, general claims of environmental benefit are difficult to interpret and, depending on their context, may convey a wide range of meanings to consumers," and I think the same thing would apply here that, you know, in general benefit claims or general safety claims of products, you know, traditionally, general safety claims for pesticide products have not been allowed and are not allowed, but whether -- where we got to with the environmental marketing claims with FTC, we're coming up with a few designated specific measurable, verifiable types of claims in setting the criteria for making those claims, including claims of biodegradable, refillable, recyclable and where

there was very specific criteria.

Some of those claims are already being used on pesticide products such as refillable, such as the ozone depletion claims or lack thereof, ozone friendly-type claims, those are already being used and are already being specified, but I think an area that I would like the agency to consider is looking at, again, safety claims and not general, inherent product safety claims but more specific safety claims, and if you can go to the next slide.

And this is looking back to the consumer labeling initiative, and I'm going to focus a lot on consumer labeling and consumer claims because the consumers rely on label claims more than, I think, other users for making their product decisions, and when we did the consumer label initiative, we surveyed three categories of products, hard surface cleaners, indoor insecticides, and outdoor pesticides, and in those three categories, consumers indicated what they want -- the information they want. They want directions for use. They want a description of what it does. They want a description of where not to use the product. They want information on --

on health and emergency information. So, these are the information they said as most important. Next slide.

They also gave us the information they considered least important to them. This was -- and the information that they least often read on product labels, and interestingly, and this was a surprise when we did this survey, in all product categories, the most often considered least important and most often considered never read was positive environmental claim statements, and so this was sort of a surprise because we -- you know, we would have thought that that was more important to consumers, and you can see other -- they also don't think the name of the manufacturer is very important, but that's not really very surprising.

(Laughter).

MS. SPAGNOLI: But actually the name of the manufacturer was more important than environmental claims. So, that was rather -- like I said, very surprising. Next slide.

But another interesting aspect is when deciding what products to purchase, what kind of information do you look for? And this, again, looking at all three

categories, what was the most important things they were looking for, and again, they wanted -- there -- and these -- these choices included -- there were some environmental type claims.

I -- you can see no CFCs was one of them, no phosphates. Other environmental-type claims were included in these choices, but in most cases they were not deemed the kind of information that consumers looked for in making purchases.

They wanted more to know was the product going to hurt where I'm going to put it? Is it going to be safe to where I'm planning to use it? Is it going to hurt my plants? Is it going to hurt my pets? Is it going to hurt my, you know, carpet?

So, again, it seemed like consumers were very interested in looking at product characteristics very specific to the use of the product. Next slide.

So, you know, what's wrong with the word safe? This has been kind of -- you know, safe has been the four letter word of pesticides. Regulations at 40 C.F.R. state that, "Any claims made with regard to the safety of a product or its ingredients are considered false or

misleading," and that, you know, could be true that nothing is inherently safe in all circumstances. You know, even water is not safe in every circumstance, but it wouldn't preclude, nor would it be false and misleading to indicate that a particular use of the product is safe for where it's intended to be used, and by telling consumers what is a safe use of the product, it may help ensure the proper use and help consumers select the product that is for the uses they intend it for. Next slide.

I'm going to use an example of one our products, and just from Bayer Animal Health's perspective, about 50 percent of our products are pesticides, and about 50 percent of our products are animal drugs, and the animal drugs being regulated by FDA routinely make the claim of safe and effective as used -- when used as indicated, I think is, you know, generally the terms.

So, there's a little bit within our consumer base even with that -- with veterinarians a little bit of, you know, this product is safe. Is this product safe? And so, there's a little bit of confusion there because the products, you know, are basically looked at similarly, but they don't make the same types of claims.

So, our current label on this particular product is intended only for dogs, and it says for monthly use on dogs and puppies seven weeks of age and older. Do not use on cats, but you really don't get an indication of why you shouldn't use it on cats. You know, the perception might be, well, they want you to buy the cat product instead, but you know, it just basically just says do not use on cats. Next slide.

But if it said safe for monthly use on dogs and puppies seven weeks of age and older. Do not use on cats, I think it sends a different message. The message it now says is it's safe to use on dogs and puppies seven weeks of age and older, indicating it's not necessarily safe to use on puppies younger than seven weeks of age and older, and it also indicates it's not safe to use on cats.

So, I don't think that this is a misleading statement as to safety of the product. In fact, I think it helps clarify where the product shouldn't be used and why, that it's not safe for these uses.

So, you know, what we've seen is that consumers want to know where and how products can be used safely, and how best can we communicate this?

And I would say that, you know, these would be -- as we found with FTC on the environmental marketing claims, it would need to be claims that are very specific, factual, and verifiable that you have data to say the use of this product will not harm bees, this product is safe for use on roses, the product is safe to use on hardwood floors and cabinets in all cases that there's specific data that can show that that claim is true and next slide.

What I think that the agency would avoid in this area if they were going to look at it, as did FTC, very -- you know, the same way that FTC indicated, is, you know, general, unqualified claims, an environmentally friendly product. I think this product specifically, you know, grass and weed killer -- I'm not trying to pick on it, but it says environmentally friendly on the label. I think that's a difficult claim to qualify or to prove, you know, something naturally safe -- you know, something safe just because it's natural or it's naturally safe, you know, good for Mother Earth, just these general, unqualified benefit claims --

(Laughter).

MS. SPAGNOLI: -- I think that -- you know, we

went through this, and again, it's almost like going through what we went through 12 years ago when we hashed this out with -- in particular with mostly cleaning products, I think, at the time, you know, with biodegradable and environmentally friendly, but you know, that these kind of unqualified claims generally just are too hard to -- too hard to regulate, too hard to qualify.

So, you know, why do I think maybe the agency should pursue this? You know, I think providing consumers and other users with information that helps them choose the products that best suit -- best suit their needs and concerns. Again, what we heard from consumers in this research, here's what I look for when I got to purchase a product. I think it would help consumers also use the products properly. If they know what it's safe to use on, they're going to be less likely to not use it where they know it's not safe.

Setting guidelines, I think, for specific types of claims will help ensure consistency and clarify as opposed to right now, I think a lot of manufacturers use innuendo. They'll say the product is gentle. They try to get the message across in indirect ways, and I think

that's -- that creates an opportunity for more confusion than if it was a very clear, concise type of claim.

I also think it creates a more level playing field with products with similar attributes. I know a lot of, you know, consumer products companies, in particular, have had some issues with 25B products because they are making claims they are not allowed on conventional products even though they may have some of the same attributes.

UNIDENTIFIED FEMALE: Okay, Paula.

MR. JONES: Okay.

PAULA: Okay. You can go to the next one, and the next one, and the next one. Okay. Thank you for inviting me to participate in the panel discussion today because Scotts Company is the leading marketer of consumer lawn and garden care products is extremely interested in this environmental marketing claims issue because we believe such claims will help increase and promote product stewardship and benefit the environment.

UNIDENTIFIED MALE: (Inaudible).

PAULA: Okay. History has shown that consumers do change their behavior for the benefit of the

environment when they understand the impact of their actions. We saw it in the '70s with pollution and litter prevention from the crying Indian. Recycling didn't exist years ago and now it's prevalent.

Motor oil disposal is another behavior that consumers have changed and forest fire prevention. So, when these consumers are motivated to change the behavior to benefit the environment, alls it takes to accomplish that is an effective education program.

Fortunately, our current registration system requires label statements that consumers just -- just don't understand. For example, the single most popular product for lawn care in America contains the following statements: "Do not apply when weather conditions favor drift from target areas."

"Drift or run-off may adversely affect non-target plants." "Do not contaminate water when disposing of equipment wash waters." These statements do not -- are not effective at changing consumers' behavior or influence them -- them on what actions to take.

Our goal is for the consumer to select the right product and to read, understand, and follow the label

directions, and from what we learned from the consumer labeling initiatives, this technical information that does not instruct the behavior actually discourages the consumer from reading the entire label. Okay.

Also, at Scotts we know, because we have a help line that receives more than 800,000 calls from our consumers every year, that information tells us that "do not" instructions are not as reliable in promoting environmental stewardship as positive statements.

For instance, "Do not contaminate water when disposing of equipment wash waters," what are we talking about there? We're talking about where do you rinse your spreader or you rinse your application for a liquid, but a consumer, absent a clear statement, he's up to his own devices on what he's -- what -- what do we mean by this?

What we really mean to say is rinse the spreader over a patch of health turf so that the run-off does not flow into a curb, gutter, or stream. Oh, okay. I get that, and maybe I'll change my behavior if -- why didn't you tell me? So, that's the situation that we're in.

We expect the most positive environmental impact will be achieved by addressing environmental issues using

consumer language. We also think we need to do three things on a label. The label is big, messy, and small font, a lot of information.

You have to get the reader's attention. We have to convey to them that their action does make a different, not the do not, and we have to explain the action that we want them to follow. Okay.

A couple of examples that we've just mocked up to illustrate what I mean here, to get the person's attention -- you know, they like pictorials, but there's the word "safe". That gets people's attention because they inherently want to be safe, and they want to do -- do the right thing.

So, in our idea here is to get their attention, we address something that's top of mind, water resources, and how do you keep your World safe? Well, gardeners are inherently care for the Earth, they really do.

So, what we want to do is educate them, get their attention by a title line and then show them what they should do -- what behaviors we would like them to follow to benefit the environment, that would be mowing the clippings into the street is a bad practice. It ends up

in the storm drain, which goes to the water body, which should go to a -- to the bottom of a pond where it rots, and chokes, and grows algae, and consumers don't want to do that, but they don't understand that there could be a connection.

We also would use such a section to communicate what the -- what actions we want to consumer to take, which would be sweep up any product from the hard surfaces. Keep the clippings and leaves off streets or sidewalks, and when finished, return the excess product to a bag and rinse the spreader over the lawn.

I want to take an opportunity -- if a consumer can only capture two or three bits of information, we should prioritize what information is most important for them to follow to benefit the environment.

I have another example, "Join Scotts and be a good neighbor to the environment." Well, that's an environmental marketing claim, but I need to use the word "good neighbor" and "environment" to get their attention or the impact will be lost.

Again, after getting their attention, telling them what's in it for them, how can they help the

environment, we could follow up with some most important examples of what the consumers should do to use this product in the most effective manner.

Okay. These examples, unfortunately, would not be allowed because at the product label review level, they would be deemed misleading. The word "safe" is in there, which can't happen, and the word "friends to the environment" is also categorically denied because none of those kind of statements can be made that can't be proofed, and they imply safety.

So, we're in a situation where we really need to overcome some of the barriers that we've put up in our communications to the consumer, as we're stuck with language that's mandated and really never changed.

Steps forwards, I suggest -- or I agree with the discussion so far and in your preview that we need to facilitate stewardship statements on product labels. You can call them environmental marketing or stewardship, but they are statements that we can really try to help the use of pesticide products.

I would argue that EPA guidance is necessary because often a claim or a phrase made by notification to

the agency which apparent -- seemingly doesn't break any rules would be denied at a state level, and for a national company that's something that we can't manage.

So, we do need EPA guidance on this. Oh, and it can be developed, I think it's a good idea, through a workgroup or stakeholder workgroup, or registrants can be given the opportunity to seek approval of environmental claims for a policy level within the agency to avoid the categorical, conservative denial at the label review level.

To move forward, we really need policy level engagement. That's what I have.

UNIDENTIFIED FEMALE: Thank you. Mary Ellen, you want to give you the perspective from the state regulatory arena, and what I'm going to do is respond to a couple of the original questions that was posed to the PPDC from our perspective.

One of the questions was can environmental marketing claims include users' behavior, and I'd say definitely yes, but it seems to me these are claims that should already be on the label now and not be tagged as environmental marketing claims. If there is a safer way

to dispose of the product that label direction should be existing at this time.

One of the other questions was how should environmental marketing claims program work, and that's an area where we're not sure about. We're not quite sure how EPA will verify the claims, whether or not there will be risk assessments done on each product or risk assessments done between products in case there's claims stating that one product may be more environmental friendly than another, but if you were to select one of the options posed in the original set of questions, we think that the establishing a list of approved statements or claims would be the best way to do it and probably through a workgroup and get the PPDC input, as well, and questions about OPP resources --

UNIDENTIFIED MALE: Actually, bring it closer to you so you -- they don't have to amplify it so much.

MS. SETTING: Okay. Thanks. I thought I was too close. Questions about OPP resources going to this, it seems that to the -- to the states that OPP's resources would be better served in other arenas rather than in opening up a whole nother program in which to expel your

resources on. You've got a lot on your plate now with all the things we've been hearing about today, in particular, and the environmental claims arena just seems to be putting a lot of resources -- or the potential's there to put a lot of resources into a program that I'm not convinced you will get a lot of benefit out of, and I know you get sick of hearing the states whine about the 25B registrations, but I'm compelled to do that. That particular program was put on the table to help you reserve some of your resources and not expend them in ways that you thought you might be able to save, and we're afraid this program's maybe putting you back in that direction again.

And as far as enforcement, naturally being enforcement agencies, we're not comfortable with self-enforcement or enforcement through competitors. Usually when there's violative label claims there's quite a bit of documentation and paperwork that's gone into documenting problems that are referred back to EPA.

So, we think that eventually the states would be getting drawn into this, and unless it was done in the manner in which both Julie and Paula have proposed that it

be very specific label claims that could and could not be used, and that was made very clear. We pretty much just feel this is a path we probably don't want to go down.

UNIDENTIFIED FEMALE: This is the question that we asked the PPDC the last time we were here and the question we're back to, and first, I guess I should ask are there any comments that folks want to make to clarify -- any questions to clarify? Yes.

UNIDENTIFIED FEMALE: I just wanted to comment that I thought they talked a little bit about different things because what Julie was talking about, in my opinion, was influencing a purchasing decision; whereas, what Paula was talking about was influencing practices after purchase, two very different things, and as a consumer, I really kind of resent the mind games and techno-mumble that they put on labels, but what Julie -- the other person was talking about makes a lot of sense. So, those are my thoughts.

UNIDENTIFIED FEMALE: Any other clarifying questions or comments?

UNIDENTIFIED MALE: Just to follow up on what Lori asked, can you go back to Paula's slide? Go back a

couple slides, the one about -- no, not that one --

(Laughter).

UNIDENTIFIED FEMALE: But that's a nice one.

UNIDENTIFIED MALE: (Inaudible). Let's see, are these -- is this an environmental claim?

UNIDENTIFIED FEMALE: Helping keep the World safe, I think and just to --

UNIDENTIFIED MALE: Is that what we're saying?

UNIDENTIFIED FEMALE: -- clarify --

UNIDENTIFIED MALE: Is that one and the other one environmental claims?

UNIDENTIFIED FEMALE: I don't think that's what we perceived when we started this discussion --

UNIDENTIFIED MALE: Right.

UNIDENTIFIED FEMALE: -- but I think that what Paula is proposing is an alternative thing, information that could be put on labels and they could help us get environmental benefits, and I think we're sort of, you know --

UNIDENTIFIED MALE: But are we saying something like that or the one afterwards, are those environmental -- I just want to be clear what we can and can't say

currently.

PAULA: We can't say this. I'm not confident that this would be able to be put on a package for national distribution.

UNIDENTIFIED MALE: Okay. What about the next one?

PAULA: Nor the next one, "Be a good neighbor to the environment," that's an environmental claim.

UNIDENTIFIED MALE: But it's the wording -- it's the wording in the tag line, it's not necessarily the suggestion?

PAULA: Right.

UNIDENTIFIED MALE: Okay.

PAULA: And what -- what we're saying is you need both.

UNIDENTIFIED MALE: Okay.

PAULA: Our labels are full of the underneath stuff.

UNIDENTIFIED MALE: Okay.

UNIDENTIFIED FEMALE: And also, too, the other -- the initial language that you've provided is actually boilerplate.

UNIDENTIFIED FEMALE: Yes.

UNIDENTIFIED FEMALE: I mean, it's part of the --

UNIDENTIFIED FEMALE: Yeah.

UNIDENTIFIED FEMALE: -- that's what you get.

UNIDENTIFIED FEMALE: Go back a couple more, there, that --

UNIDENTIFIED FEMALE: Yeah.

UNIDENTIFIED FEMALE: -- right there, I mean, that --

UNIDENTIFIED FEMALE: Do not contaminate --

UNIDENTIFIED FEMALE: -- do not contaminate is boilerplate.

UNIDENTIFIED FEMALE: -- is boilerplate. That's just (inaudible).

UNIDENTIFIED MALE: And is -- but can we --

(Tape 5, Side B.)

UNIDENTIFIED FEMALE: You have to --

UNIDENTIFIED MALE: Can we say the -- can we say versus? Can we say the second statement?

UNIDENTIFIED FEMALE: No. The first one is required as part of the --

UNIDENTIFIED FEMALE: No.

UNIDENTIFIED FEMALE: -- registration of one of the active ingredients. So, that's the statement that must appear on the label.

UNIDENTIFIED MALE: I understand. Can you not say the second? I'm just asking.

UNIDENTIFIED FEMALE: (Inaudible).

UNIDENTIFIED FEMALE: I -- I -- I think over the years, we have definitely developed boilerplate. On the other hand, registrants --

UNIDENTIFIED MALE: Yeah.

UNIDENTIFIED FEMALE: -- do come in with alternate wording for things, and I like -- I would like to believe that if we saw somebody come in with the second statement there, which is in plain language -- I think my husband's actually put Paula up to this --

(Laughter).

UNIDENTIFIED FEMALE: -- he -- he's always saying to me, "Why do you say it this way? You must want me to misuse the product." No. No. No. That's not, but it's a factual statement, and it -- it conveys the same information, and for many of us, it conveys it in a different way.

It doesn't mean that we wouldn't have somebody somewhere who said, eh, it's not exactly what was in the label review manual, but I think most of our label reviewers would recognize that --

UNIDENTIFIED MALE: Okay.

UNIDENTIFIED FEMALE: -- as an alternate factual way to cover the same --

UNIDENTIFIED FEMALE: But --

UNIDENTIFIED FEMALE: -- requirement.

UNIDENTIFIED FEMALE: -- I just received a letter the other day that denied commonsense language --

UNIDENTIFIED FEMALE: Well --

UNIDENTIFIED FEMALE: -- over the boilerplate language, and you know, we -- we intend to pursue it, but that's why we need this EPA, you know, policy guidance to -- to allow that, or else at that review level, we get denied, and at the state level, it's even worse.

UNIDENTIFIED MALE: And I can tell you unequivocally that a reviewer would not allow that second statement and would say you've got to go back to the boilerplate because that's what they do.

To answer your question about the whole program,

what do we think? I think it's great. I think we really need to do it. I'd love to see the PPDC get involved. I'd love to be part of a task force to be involved in it. I think it's something that really we should move towards and not just in consumer products but all the agricultural forestry, everything, because there's a lot of misconception out there, and I'd love to see this opened up and get away from some of these boilerplate things which don't make much sense. In fact, I'd like to see it extended even further to maybe talk about some of the signal word things because right now we have four toxic categories, three signal words and -- and you know, to them, what is the difference between caution, and warning, and danger really doesn't really mean a lot. I wish we had some better verbiage in the middle there someplace or to the left or to the right of it. I would love to see us pursue this.

UNIDENTIFIED FEMALE: Why don't I start at this end here. Rebeckah?

MS. FREEMAN: Probab -- given all the other stressors on the agency this may not be where we want a majority of resources going at this time. It certainly

would be something that for a good faith effort to make the user community feel a little more in touch with the agency, I think that the notion of using plain language, obviously, given liability concerns and considerations in how you say things but the notion that you simply can't use the word safe, or you can't ever use the word environment, or there are so many other things that seem to be catching things in the cycle, plain language on labels from the agricultural perspective who are probably more sophisticated users in most circumstances, and then the residential users, I think, would be much appreciated, which one of the biggest complaints that I get if I'm just at a normal, average farmer kind of meeting is they are going to do something else to the label, and I'm going to have to try to figure out what that means, too, or you know, they're going to say something else in another way, and then I'm going to have to go ask an extension agent what the heck they mean. You know, they're going to tell me what not to do, but you never tell me what to do, and just for my father's sake, he's made the same comment, and he is a residential user.

So, I've had to interpret several labels for him

and he's a very well-educated, intelligent grown man. So, I think it's -- it's definitely something worth consideration.

MR. JONES: Amy.

UNIDENTIFIED FEMALE: Oh, Amy.

UNIDENTIFIED FEMALE: Amy.

UNIDENTIFIED FEMALE: Oh, thank you.

UNIDENTIFIED FEMALE: I have a clarification. It's unclear to me right now if we're talking about -- when we look at the boilerplate language versus language that's simpler for the consumer to understand, that seems to me to be a little bit different like your statements about don't rinse -- or rinse of on a -- you know, a clean -- a health piece of turf versus safe or environmental friendly.

So, are we -- those are two different things; correct?

UNIDENTIFIED FEMALE: I -- we thought that they were all linked together because right now, they would be, you know, denied for the same purpose. Well, it could be misleading. You could be -- the environmental claims aren't allowed because it could be misleading.

So me instructing the consumer to join us in safe behavior could be interpreted as, oh, this product is safe. It's making a safety claim, and we just would rather leave that up to vagary and not say anything about it.

So, what -- you know, the question before this committee is do you want to get into the idea of an environmental claims study, and what -- what we're communicating is that you, indeed, should, because without doing that, we'll -- we'll -- we won't ever get into these other -- other areas.

UNIDENTIFIED FEMALE: I think you're looking at the difference -- some of the differences -- claims that are put on a product to market the product versus claims that are put on the product principally to address behavior of the user, and I'm seeing those as being sort of -- sort of a difference that we're seeing here in the discussions and -- and discussions by some of the industry folks, and that's a question of PPDC.

I mean, maybe you want to pursue one and not the other or -- or look at a number of options. So --

UNIDENTIFIED FEMALE: Carolyn.

MS. BRICKEY: Yeah. I think there are two different issues, and I think you need to pursue them separately, and there's a whole bunch of reasons why, but like if you go back to Paula's slides where she -- the one be a good neighbor to the environment, if you left Scotts out of that -- and don't be offended by me saying this, it's not an environmental claim. It's saying here's things you can do -- not that one, yeah, the next one -- be a good neighbor to the environment, that's telling the consumer what the consumer can do without Scotts in it, and then that's not an environmental claim, in my judgment --

UNIDENTIFIED FEMALE: Well, but --

MS. BRICKEY: -- the one before --

UNIDENTIFIED FEMALE: -- but -- but what -- I --

MS. BRICKEY: Wait a minute.

UNIDENTIFIED FEMALE: I hear what you're saying, but --

MS. BRICKEY: Wait a minute. Wait a minute.

UNIDENTIFIED FEMALE: -- what -- what's --

MS. BRICKEY: Let's look at the one before. Okay. This just says water resources, help keep the World

safe. Scotts is not in there, and that's not an environmental claim. So, I think we could resource this topic pretty quickly there and approve a boilerplate list of things -- wait a minute, just -- I got to finish this.

(Laughter).

MS. BRICKEY: I think we could -- we could finish that discussion pretty quickly as a group and decide that, you know, you ought to pick out, you know, 10 boilerplate things that you allow people to say that direct consumers specifically about what to do, that's not difficult. Where it gets more difficult is allowing -- allowing the marketing claims, and I think they can range from help Scotts keep your World safe to the, you know, the greatest product ever made kind of claims, and you get into that whole issue -- what's it called when you make a claim that's just fuzzy and just feel good --

UNIDENTIFIED FEMALE: Fluff.

UNIDENTIFIED FEMALE: Puffy.

MS. BRICKEY: Puffery, yeah, you get into puffery and all those kind of issues and it's a lot more complicated. Now, I don't say that we shouldn't look at the marketing claims. I mean, I'm -- I'm actually in

favor of that, but I just think it is much more different and complication than what we're talking about here.

Just a clarification, you mean that you would think that this would be okay to put on the package without -- if the word Scotts was off it --

MS. BRICKEY: Yeah, in that -- in that tagline, yes.

UNIDENTIFIED FEMALE: Okay. Okay.

MS. BRICKEY: Mmm-hmm.

UNIDENTIFIED FEMALE: I guess I feel that's subjective. What about Scotts in the line makes you think that it's a marketing claim but absent it you're fine with it, without a real --

MS. BRICKEY: I'm glad you asked me that question.

UNIDENTIFIED FEMALE: -- I don't understand your logic, you know.

MS. BRICKEY: Because I don't know that because Scotts made a product and somebody is going to use it on their lawn that it's going to help keep the World safe, give me a break. That's way over the top, don't you think?

(Laughter).

UNIDENTIFIED FEMALE: How did you get that out of that?

MS. BRICKEY: It says help Scotts keep your World safe, that's where I get it.

UNIDENTIFIED FEMALE: But it will -- it will be on the bag in either case, the same bag.

MS. BRICKEY: Help water resources --

UNIDENTIFIED FEMALE: Yep.

MS. BRICKEY: -- or help keep your water resources safe --

UNIDENTIFIED FEMALE: Yes.

MS. BRICKEY: -- I don't care what you say, but it's still --

UNIDENTIFIED FEMALE: Okay.

MS. BRICKEY: -- a -- it's still instructions to the consumer about what to do --

UNIDENTIFIED FEMALE: Okay.

MS. BRICKEY: -- to be a good consumer --

UNIDENTIFIED FEMALE: Right.

MS. BRICKEY: -- or a good fellow citizen, or whatever. That's quite different from putting Scotts in

there. Again, no offense to Scotts. It could be some other product, but -- but I understand why you want Scotts in there. I mean, I'm not that naive. I just think it's much more difficult and complicated, and I think there are very big issues connected with those two words up there, Scotts and safe legally. They give EPA a lot of heartburn, and I just don't know that you're ever going to get agreement between EPA and FTC to start making those kind of claims. Maybe I'm wrong, but I think it's very difficult.

UNIDENTIFIED FEMALE: Amy.

UNIDENTIFIED FEMALE: As a pesticide safety educator, I would say that you are definitely talking about two different things here in the first two presentations. The first one is something that generally we stay away from in pesticide safety education because it implies that a product or a chemical is safe and another product or chemical is not safe.

I know that's not exactly what you're saying, and you were arguing for very specific language, but it helps sort of -- it, unfortunately, undercuts what we teach that there are safer ways to use products and ways that

minimize adverse effects on the environment and on human health.

This approach, I agree with Caroline, if you -- if you have the word "help Scotts" in there, it implies that Scotts already is keeping your World safe or whatever company, that the company is already keeping the World safe and just needs a little help from you.

If you leave it with help keep your World safe or, better yet, some -- I hesitate to use the word safety tips but safe use practices, best use practices. We call them best management practices, best use practices, things like that, and then the three things that you've identified there, that's classic safety education which we teach in our classes, and if it could be extended to be actually put on the label, it would be wonderful.

MS. BRICKEY: Right, and that's what -- and I agree for people who are familiar with products and who are willing to read -- that enters into the technical. We struggled with responsible use tips. Well, that's not attention-getting for the consumer, and you need the consumer to embrace the issue --

UNIDENTIFIED FEMALE: I understand what you're

saying.

MS. BRICKEY: -- we are looking for ways to do that.

UNIDENTIFIED FEMALE: And I'm not opposed to the wording "help keep your World safe" --

MS. BRICKEY: Right.

UNIDENTIFIED FEMALE: -- but that's for the agency to decide whether that makes up a claim, but the other one definitely does make -- to me is what you're talking about when you talk about environmental marketing. This, if you word it carefully, could be seen as helping the consumer or the applicator make a better decision about how to use that product safely.

PAULA: Can I respond to -- to just that one -- you know, in the standpoint of saying that -- that one product -- by saying a use of one product is safe implies that another product is not safe may be the case.

Now, you know, we also do have a product that's intended for use on cats and kittens, and if we say on that product "safe for use on cats and kittens" that's because it is, and yes -- and this other product is not. So, yes, you are making the claim that this product is

safe for that use and the other product is not. So, I think it's -- again, I -- and what we see happening now, and -- and you know, is it clear to the consumer if you say safe for use on puppies than if you say gentle enough for use on puppies.

I mean, and you know, is it -- when you're trying to convey a message, is -- I think it's better to convey that message truthfully and specifically, and if it is -- and if it is for a product comparison, it may be a valid product comparison: I shouldn't use this product on cats, but this one is safe for cats.

So, I think it -- it can go both ways.

UNIDENTIFIED FEMALE: Okay. Patti.

MS. BRIGHT: I'd just like to comment on the second one. As Rebeckah said, you know, there's a lot of priorities for OPP and how much -- you know, how much money, and time, and resources do you want to put into something like this, but I think it's probably something you could do without putting a lot of resources in, and it would probably be something that would go a long way in reducing the impacts of pesticides. When I was in veterinary practice, a lot of times we would see pets or

wildlife that would be brought in because someone had not followed the instructions.

I don't think it's that they were intentionally ignoring them, it's that they didn't understand why they were important, for example, with diazanon (phonetic), you know, they sprinkle the granules out there and the package says water thoroughly, and people say, well, it's going to rain tomorrow. I won't worry about it, and then a bird goes out and picks it up, or the pets go out and pick it up.

So, I think if people had a better understanding of the implications of why the grass shouldn't be in the road, they would follow that, and I think it's something you could -- you know, you couldn't certainly make some changes with without a lot of resources.

MR. LIBMAN: I have to say that I thought Paula's made so much -- so much sense it was frightening. I mean, I -- I think that if you can -- I think one of the things -- and Patti just hit on this -- is you can't examine this language in a vacuum. There is language there, and we saw some of it up in that presentation, and it's not very understandable, and it's not very meaningful to consumers,

and I work with consumer products companies all the time that are -- that are encumbered by their inability to sensibly articulate the benefits of their product to their buyers because we're working with very tough boilerplate language that really isn't very meaningful to anybody who's reading it, and probably most people aren't reading it.

So, I think at a minimum here, and I'll grant you that Julie's side of this has a little bit more of a slippery slope maybe than Paula's does, but I think at a minimum, I would really like to see the committee devote some time through a workgroup toward getting into these issues, and I think it's not going to be terribly labor-intensive, and that's why you've got a committee like this.

UNIDENTIFIED FEMALE: Mary Ellen.

MS. SETTING: I just wanted to follow-up on Gary's comment that -- well, first of all, I was directing my comments more towards the -- the marketing claim as a marketing advantage where one product would be perceived as safer over another, but the boilerplate language is an absolute necessity. The boilerplate language probably

needs to be changed so that it is more understandable, but we -- one of the reasons we've spent four years fixing the mosquito control -- trying to fix the mosquito control labels is we found that statements were all over the board between products, and we -- we find an enforcement when you've got similar products with the same active ingredient, different brand names but different label directions or precautionary statements.

If you don't use that boilerplate language, we have an immense enforcement problem because then applicators start taking language from one label or another, whatever suits their needs, and that absolutely doesn't work. So, we do need the boilerplate language, and I -- my question is the proposal that Paula made makes absolute sense, but is the pesticide product label really the place for this information. You know, the labels are supposed to be there to direct a user how to use the product, and I'm just afraid if we dilute that label with too much information, it -- the -- the specifics on how to use the product will be lost forever.

UNIDENTIFIED MALE: Dennis.

UNIDENTIFIED FEMALE: Dennis. Thank you.

MR. HOWARD: Yeah, and on the enforcement side, too, some -- some of these statements, they intuitively sound fine, but if you put your pesticide inspector hat on and go out to a complaint, first of all, you're asking an inspector, just to use Paula's example here, to be able to identify what healthy turf is versus unhealthy turf.

You are asking an inspector to -- to determine whether you're a good neighbor to the environment. You're asking them to determine whether you're helping to keep your World -- World safe. Those are directives, basically.

They are not -- they're not really guidance, and so while -- while some modification approach may -- may be helpful, I think it's real important to remember that not only are consumers affected by the changes that are made in these -- in this language, but state programs are going to be impacted, as well.

UNIDENTIFIED FEMALE: Susan.

MS. HALL: As both a consumer and a stakeholder on behalf of PITA and animal rights issues, I have sort of a comment and a question because I don't purport to know that much about labeling, but to sort of take off from

what Mary Ellen said, it occurred to me that -- and I just had the experience the other day of trying to read the label on the back of a product that, you know, first of all, I had to pull out the magnifying glass, and I was concerned because I wanted to make sure that my cats weren't going to, you know, be in trouble or that this wasn't going to ruin my garden, and -- and that, you know, it's like -- it's so user unfriendly, all that language, and I assume that it has to be there because of some regulation, but nothing that I saw up there on the screen to me seemed even close to puffing, it just was an easy read.

So, what I'm asking and suggesting is is it inconsistent with EPA regs to have a -- you know, an insert with -- with your product that is in plain English that, you know, that you could read. I would appreciate being able to read wash your spreader instead of don't contaminate the water. Don't contaminate the water, well, you know, how do I clean it? I -- I can't use water. You know, so -- you know, that's my question/comment.

I would really love to be able to skip that -- that stuff on the back of the product and read something

in plain English. Secondly, I think that what Mr. Quinn said is what occurred to me as this issue was being raised that this -- this, in itself, could be -- you know, take a whole advisory committee because I think it's really important, and I think it's really something that consumers are interested in, all kinds of stakeholders are interested in, and oh, as a last thought, I would like to also be able to see really quickly on a pesticide product, you know, what effect it's going to have on companion animals, and I'd also like to -- although, I don't know if it's possible, I'd also like to know if something has not been tested on animals. That's -- that's the way I buy cosmetic products, and I don't know if it's at all feasible with -- with pesticides if there is such a thing as a pesticide that hasn't --

(Laughter).

MS. HALL: -- but, okay. Well, there's a pipedream there. Thank you.

UNIDENTIFIED FEMALE: We're working on it.

MS. HALL: Thank you very much.

UNIDENTIFIED MALE: So, we think Crop Life, that this has a lot of traction for consumer product labels and

a continuation of the consumer labeling initiative, but I (inaudible) I also want to be clear that we have no interest in the agricultural marketplace to go this direction, mainly because of the resources associated with this kind of massive change.

So, this -- as I think most everyone has acknowledged, a huge undertaking, and we'd rather see our industry and agency resources alike dedicated somewhere else than in this area for agricultural products.

The other obvious thing that is important is for agricultural uses, the label is the law, and there's a tremendous amount of case law and precedent out there, and again, from a resource standpoint, we wouldn't be interested in having to make that transition, but we do support it from a consumer standpoint.

UNIDENTIFIED FEMALE: Dr. Lockwood.

MR. LOCKWOOD: Thank you. Well, I agree with those who said that we're talking about apples and oranges in this -- in this issue. I definitely believe that we should take advantage of what psychologists and linguistics can tell us about how people read and understand material that's put in front of them so that

consumers can make best and proper use of products that they buy.

As the chairman of the institutional review board at my medical center, one of the constant jobs that we face in reviewing proposals is examining the informed consent document and getting out the language that usually lawyers put in there that make things almost incomprehensible for someone who may be considering volunteering for participation in some kind of a medical research project.

At the same time, I think we also have to be cognizant of the fact that, at least the last time I checked, the pesticide industry is something like a 12 billion dollar per year industry is very competitive. Undoubtedly, different companies sell the same active ingredient under different brand names or in different products, and I think we have to avoid a situation that's sort of akin to the Bud Light versus Miller Light wars that you hear going on now or things that you see on your evening news sort of like ask your environmental, agricultural specialist what turf builder can do for you --

(Laughter).

MR. LOCKWOOD: -- as sort of like the -- like unnamed drugs, you know, ask your doctor what --

(Laughter).

MR. LOCKWOOD: -- x, y, z can do for you, and I think we have to bring some commonsense and -- and better understanding of how to use products, but at the same time not open a Pandora's box of competing, extravagant use claims that ultimately won't serve the -- the consumer, the public health, or environmental protection but may work to the advantage of one company over another.

UNIDENTIFIED FEMALE: (Inaudible).

UNIDENTIFIED FEMALE: I've heard several different people talk about the differences between the communications objectives, but I would like to clarify that in communication there are different kinds of communication and in advertising their communication objective is to sell, and in education the communication objective is to teach, and I think it would be good to keep those two separate when we're discussing this.

Several people have brought that up, but I just wanted to clarify.

UNIDENTIFIED MALE: Yes, and just a comment FDA's foods, not drugs perspective and that's again, I think, you're looking at marketing versus how to use products. It is very critical and we do it all the time trying to figure out how do we give advice to consumers that they're going to understand. So, some of those points were very simple.

I mean, maybe there was a little -- the banner wasn't maybe just right, but it's very important to be able to communicate what consumers should do, but they need to know what's the problem? Why should I do it?

So, why should I do it, and what should I do, in very simple terms, and we use focus groups all the time to try to test different messages, basics messages. One approach has been to, you know, give typical labeling, and people can work around that kind of -- that kind of approach or the -- or criteria for -- they need to meet for such labeling.

I'm not quite sure what the concern about use of the term "safe" is because for food additives for years, we, of course, we determine that food additives are safe for the intended use. Safe is reasonable asserting of no

harm, and -- and it my understanding that in the FQPA, the same definition was adopted. So, if -- if you -- it's really focused on safe for the intended use, I would think that that terminology could be used. Consumers understand that.

Yes, they think in black and white, it's either safe or not safe, but as -- as -- as -- insofar as a simple way to convey things, I think your focus groups would probably tell you that they would understand that -- that better, and I think the focus groups need to -- you know, how do you get -- get the message that you want, the behavior that you want? That's the key. Carol.

MS. STROEBEL: I hope I can remember everything that I wanted to say that a lot of other folks here have already touched on a bit, and I guess I'll just have to try and say what Garrett was going to say so that he won't have anything to add.

(Laughter).

MS. STROEBEL: And the conversation has gone around -- because I certainly agree with folks that it looks we are talking about two different things, the difference between marketing claims to sell and maybe

what's said in relation to behavior, you know, product use, and so I agree with Susan Hall, and Allen Lockwood, and Melody, and you know, and I -- certainly, there is concern about misuse, and it would be great to know that the information that consumers get is the clearest possible and we're really encouraging people to do that right thing and discouraging the improper use, but I also have been hearing here is the concerns about what's on the label is kind of anecdotal that people -- their own experience in reading the label, their concern that -- that -- that the labels aren't clear or that if we were to allow different kinds of statements that we would expect that behavior would improve, and I think that the idea about focus groups, getting additional input, getting additional information from folks who -- who can -- who know about behavior -- I think most of us here are not here because we know about marketing or communication on -- in these areas, and I wasn't at the previous meeting when we talked about this, but I would be very interested in knowing if the agency had kind of baseline information about is there really a problem that needs to be fixed. I mean, it certainly sounds like it, but do we know -- does

-- or could the agency provide information or have they provided information about how many people do read the label? Do people understand the label? How do they interpret the label? What kind of misuse may be occurring for us to really begin at a point we can say, yes, there is or isn't a problem, and then we -- before we start looking to add things or change things that may be a better use of resources to understand.

UNIDENTIFIED MALE: I'll be quick. To add onto to her -- her list, I think that probably the major problem with pesticide labels with homeowners is if they read the label in the first place, when -- it has been my experience that with chemical distributers, and veterinarians, and other type of products what usually happens is they will go in and talk to their local Lowe's man or their chemical distributor and say, "I've got a weed problem. What do I do to get rid of it," and they say, "Use this," and they'll read the label so they know how much to mix, and that will be about the extent of it.

It has been my experience that when you have a homeowner that wants to wash out their spreader, they go

to the nearest storm drain to wash it out to get it off their land as fast as possible because they don't know what's in it and they don't want to touch it as much as possible because they know it's a pesticide, and pesticides we hear that, you know, you're not supposed to touch them or -- or whatever. That's the typical stigma that follows pesticides.

I think that Paula has a -- made a good point, but I think that the -- all the information that is on a label currently can stay there, but really what needs to be done is a point where the attention needs to be brought to if you want someone to change their behavior and not to go that storm drain to wash out their spreader, then you need to put a big label up there with some pictures on it that draws their attention to it, and it says in big letters this is what you do to whatever to properly wash out your spreader, and they will do that.

If you put it in six point font on the back of the label right underneath the warnings and don't put this next to this, and that, and the other thing in the store, no one's going to read it, and no one's going to see it, and you'll have one person out of 90 that reads the label

for those purposes, but for the most part, I think especially for homeowners, that that would be the way that you would convince proper storageship of a product.

For people with commercial interest, golf course superintendents, your farmers, most of those people will read their labels, if not all of them, and follow the instructions because they need to know how to use them on a commercial scale because they have a lot more at stake, and this is what they do for a living.

So, they're more knowledgeable in what's going on, but for the average weekend warrior, they're just going to ask Bob down at the local hardware store how to use this can of orothene (phonetic), and that's what he's going to do is what that person tells him.

UNIDENTIFIED FEMALE: Larry?

MR. ELWORTH: So, where are we on this?

(Laughter).

MR. ELWORTH: It sounds as if we're clear that better language tells people what they really can do in a way they can understand how to do it, maybe understand the reason for it would be useful thing to accompany the pesticide. Whether you guys want to include it in the

label is maybe another issue or not. That's a regulatory issue.

It sounds like people are -- have some serious concerns about environmental claims, but there's another issue that I'm actually concerned about, and I'm thinking back to how I would choose a pesticide, and I was also interested in a lot of information about the properties that pesticides impact, whether it would leach its impact on beneficial insects, things like that.

Now, you really use that to choose among pesticides depending on the problem. So, I guess my question is is there additional information that people could use to make smarter decisions which is, again, slightly different from environmental claims, and I don't know -- I'm not sure what you folks want to -- I mean, I know we talked about environmental claims on this.

I don't know whether the program is interested in looking at some of these additional issues that have come up in the process of talking about the environmental claims because it doesn't sound like we need a really, big, long workgroup on environmental claims at this point. I beg your pardon. Go ahead. I'm interested in how you

all --

MR. JONES: Well, I think we've gotten a fair amount of advice on this issue.

MR. ELWORTH: Right. Right.

MR. JONES: There's a reason -- there seems to be some kind of consensus around it. I think we got to take that advice back and think about what the next steps are --

MR. ELWORTH: Okay.

MR. JONES: -- and we'd certainly keep all of you posted on what that -- what that is and some thoughts about some role for PPDC, as well. Amy.

UNIDENTIFIED FEMALE: Oh, Amy.

UNIDENTIFIED FEMALE: Just one final answer to Larry's question about how -- how you get these messages across. There's a limited amount that you can put on the label, even if EPA goes for stuff like this for consumer labeling -- or for consumer marketing, and I'd certainly support Jay's comment that you stay away from it in agricultural labels because there's just too much to put on there, but even with the homeowner market, you can't put everything on there, and the way that you do that is

through educational programs so that they do understand. You work through master gardeners who work through others with contact.

You work through the Home Depots and the Lowe's so that they have the outreach to the people because that's where your homeowners are going for their advice.

MR. JONES: Julie, did you have another --

MS. SPAGNOLI: Yeah. Just a closing comment, a number of people have made reference to, you know, that consumers just don't read labels, but I think what we found in the consumer label research -- consumer labeling initiative was consumers do read labels for some products more than others.

They tended to read labels for household cleaners less than they read them for outdoor pesticides, but in general, majority -- overwhelming majority of consumers do read the labels.

We also, though -- the information, I think, that we got from that, further, was what information on labels do you read, and there was definitely, you know, a differential in the kinds of information, specifically, what are they looking for, and what information do you

read, what information don't you read, and I think maybe that can give us some indication of where -- and the reasons why they didn't read the information like ingredients, you know, I don't know chemical names or -- you know, so there was reasons why they didn't read certain types of information.

Storage and disposal was another area that kind of was, you know, a little disturbing that it was an area of the label very rarely read. So, maybe that's -- you know, that's -- you know, to Paula's -- what she kind of presented because it's not presented in a way that leads them to want to read it or to understand it, and you know, so I think they're -- I don't think it's that consumers don't want to read labels. They want to read labels for specific information, and I think we have to look at how you best provide that information for them in ways of what they're looking for and how they want to see it.

MR. JONES: (Inaudible) Terry, did you have any follow-up?

MR. TROXELL: Yes. I have a follow-up, and it has to do with Amy's point. I really don't think that going to, you know, Home Depot and other master gardener

programs is an efficient way to get -- get information out to the typical homeowner.

It's just the -- you know, what we see -- and you know, I'm also trying to think in terms of my experience with foods and all, so my experience as a consumer, but people are way to busy, and what they need is something right in their face.

When you open your bag of fertilizer to dump on the lawn that has pesticide in it, you know, it's got to be there. You know, the main points have to be there. Maybe the fine print can tell you in more detail, but if you don't get it there, people are going to forget from one time to the next. They're too busy, and that's probably -- that's one of your best chances, I think, of catching their attention.

Most people, when they spray something on pests or something, it's not like, you know, they just -- it's not like they eat food, they just ignore the label, but there's just -- they're going to look and see, you know, is this going to kill what -- kill what I'm -- I'm interested in, or is this going to -- you know, how -- how much do I put on my lawn so I don't burn the lawn or

whatever?

I think for something like a pesticide, you have a better chance of consumers following the information. Although, I do agree also with everybody that consumer -- you know, you only can read so many of the consumers through labeling. That clearly is something we've -- we've experienced. So -- but probably your best contact-point is right there at the consumer -- you know, with the consumer reading the label.

MR. JONES: I'm ready to wrap this up.

(Laughter).

MR. JONES: I think -- I think we've gotten a lot of advice here. I think we've gotten a lot of good advice. We are going to take that advice back, and we'll keep you all engaged in what we -- what we do with that advice.

I really think this was a very product session. I want to think (inaudible) and in particular, the members of the PPDC and (inaudible) for participating in the manner that you did. I think it made for a very informed discussion.

I -- I -- there's one agenda item -- well,

actually, I have to apologize -- it wasn't on the agenda. It was an oversight in our part, but in -- yesterday, as we were doing our final preparations, we realized we would have been remiss if we did not give you an update on something that's going to show up in the Federal Register tomorrow.

It has to do with the agency's response to objections we got from the NRDC associated with a number of tolerances that were established, and I think a number of you have been following this for some time. Again, it sort of has to do with the timing of the process.

It really is not -- wouldn't have been appropriate to talk about this except for that it publishes tomorrow, and we just figured that out last Friday that that's when it would publish.

So, I really didn't want any of you who were going to be going over the Federal Register tomorrow to see this and have us not having told you about it. I don't think that really would have been quite right.

So, Bill's just going to give us a five minute summary of that.

MR. DIAMOND: So, instead of reading the USA

Today, you can look at the Federal Register and find there EPA's answer to the objections that were filed by NRDC to the issuance of a tolerance for a mitaclopred (phonetic) on blueberries. The -- a mitaclopred blueberry tolerance is perhaps not a really big deal to you, but it is important to the blueberry growers, but the -- in the course of answering these objections, EPA does address a number of broader crosscutting policy arguments that were raised when NRDC filed these objections.

NRDC, in 2002, sent in a series of objections covering 14 different active ingredients and 70 different tolerances. They tended to repeat the same broad objections to the decisions that the agency had made, and we are in the process of trying to tackle each of the specific objections looking at the factual information pertaining to the particular active ingredient in tolerance.

We've completed our work on mitaclopred in blueberries and because the objections related to a temporary tolerance that has expired, we are denying the objections as a legal matter because they are no longer relevant, and the legal term is moot, but we are also

going ahead and stating our substantive position on all of the arguments that NRDC raised because, in the same Federal Register, we are issuing a new tolerance, a permanent tolerance for mitaclopred on blueberries.

Briefly, if NRDC choose to object again to this new tolerance, we will repeat our positions, and that will expedite seeking judicial review, if they choose to do so. The NRDC objections fell into four areas: One, was an objection related generally to the decision about the children's safety factor, or FQPA factor, or 10X factor.

The NRDC argued that EPA did not have enough information in order to support using a factor other than 10, and we go through each of the specific areas in which they argued our database was deficient and conclude that based on what we had, we have chosen an appropriate factor different from 10.

They argued, secondly, that we should have approached the aggregate risk assessment differently and, in particular, we should have done an assessment that focused on farm children as a specific, major, identifiable subgroup.

We go through the databases that we have relating

to whether farm children are indeed distinguishable in terms of their exposure patterns from children who live in urban areas or children who live in rural areas but not necessarily in connection with farms and conclude that the NRDC information and the other information we have available does not support treating them as an identifiable subgroup, and that in any event, we believe that our assessment doesn't underestimate exposure for any group of children, whether they're living on farms, near farms, or children of families who work on farms.

The third area that NRDC raised in their objections related to the use of toxicity data, in particular, using data from studies in which the lowest dose tested produced an adverse affect, what's call a low AL, and we argued that that's was an appropriate piece of data to use in risk assessment, and that it, therefore, supported issuing the tolerance, and then they had a number of very specific objections relating to blueberries, things like percent of crop treated information, the national distribution of blueberries, the extent to which people buy blueberries from farm stands, and so on.

As Jim said, it was signed last week and will be published tomorrow.

MR. JONES: Just a couple of points: The analysis supporting it is quite extensive. The document that's in the Federal Register is 80 pages or nearabouts. It was something that we originally published the objections and took public comment on so that there was a process for participating in the agency's ultimate decision-making, and just lastly, just for your information, NRDC unfortunately couldn't make it today.

They are a member of the PPDC. Although this wasn't the reason, we did give them an earlier heads-up, so they heard what you just heard beforehand, as we do that as a matter of course when there are -- when we're answering objections.

So, with that, we -- I believe we have one public commentor, William Meredith, who has signed up. Bill, you want to -- there's a mike right back -- Bill, if you could introduce yourself and the organization that you represent.

MR. MEREDITH: We did have a long day. So, I'm going to be real quick. My name is Bill Meredith. I'm

the director of the state of Delaware's mosquito control program, and I'm also hear to represent the American Mosquito Control Association, and I had the pleasure of speaking to this group last October in relation to the draft pesticide regulation concerning adolticide (phonetic) use.

What I really want to say on behalf of the AMCA is now that we've seen the seven recommendations associated with the draft pesticide regulation is to say thank you again, to commend the EPA for getting us to this point because were we've come over the last four years in trying to straighten out the label language issues with our control products has been a real quantum leap. We were caught, I think, in an agricultural use mindset in examining how our products are used, and that was really reflected for a long time in the language on our labels in registration decisions, in risk assessments, in mitigation requirements, and it took a while to get the message across that we had to break out of that, and I think much to the EPA's credit, the seven recommendations really helped get us there.

We still have a few problems that we'll be

commenting on within the next two months. I think there are still some vestiges or remnants of this agricultural use mindset, even with some of the recommendations, but what I really ask of any other group here that wants to comment on the draft pesticide regulation to remember this is really an attempt by the EPA to properly fit us into our own unique mode of operating. We're not agriculture. Our mode of application is much different. Our frequency of application is different. Our rate of application is different, and the EPA now, I think, has realistically reflected that.

So, if you comment, just don't try to put us back into the agriculture use box --

(Laughter).

MR. MEREDITH: -- comment on the recommendation on their own merit as they related to the real world of mosquito control, not to thinking that we're still trying to spray crops. Once again, thank you to the EPA.

MR. JONES: Thank you. All right. Well, I think we've had a pretty full day here, a lot of good dialogue, a lot of very good work by not only the staff at the agency but a number of you and others who participated,

and I thank you all for that. As -- as you are getting together tonight to go hear the cicadas, and maybe have a drink, and have dinner, I do want you to be thinking about the areas that you think would be useful and productive for us to be engaging in prospectively.

We'll have some ideas that we'll put on the table, as well. I think that, in particular, in and around endangered species how we can, as a group, tee up issues effectively for engagement would be an area, in particular, that I would like to hear back from all of you on, but the field is wide open, again, and we'll have some ideas that anxiously await some of yours, and we will be back here tomorrow at nine o' --

(Whereupon, the meeting was concluded.)

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